Exhibit 2

EXHIBIT 1

CT Corporation

Service of Process Transmittal

10/31/2019
CT Log Number 536547883

TO: Carol Purcell
Endo Pharmaceuticals Inc.
1400 Atwater Dr
Malvern, PA 19355-8701

RE: **Process Served in Delaware**

FOR: Endo Health Solutions Inc. (Domestic State: DE)

ENCLOSED ARE COPIES OF LEGAL PROCESS RECEIVED BY THE STATUTORY AGENT OF THE ABOVE COMPANY AS FOLLOWS:

TITLE OF ACTION:	CITY OF SANTA FE, PLTF. vs. PURDUE PHARMA L.P., et al., Dfts. // To: Endo Health Solutions Inc.
DOCUMENT(S) SERVED:	Summons, Complaint
COURT/AGENCY:	Santa Fe County First Judicial District Court, NM Case # D101CV201901809
NATURE OF ACTION:	Product Liability Litigation - Drug Litigation - Opioid
ON WHOM PROCESS WAS SERVED:	The Corporation Trust Company, Wilmington, DE
DATE AND HOUR OF SERVICE:	By Process Server on 10/31/2019 at 12:47
JURISDICTION SERVED :	Delaware
APPEARANCE OR ANSWER DUE:	No later than 30 days from the date you are served with this Summons
ATTORNEY(S) / SENDER(S):	Pia Salazar Salazar, Sullivan & Jasionowski 100 Gold Avenue SW, Suite 201 Albuquerque, NM 87102 505-314-1414
ACTION ITEMS:	CT has retained the current log, Retain Date: 11/01/2019, Expected Purge Date: 11/06/2019
	Image SOP
	Email Notification, Jobina Jones-McDonnell jones.jobina@endo.com
	Email Notification, Helen Howlett howlett.helen@endo.com
	Email Notification, Gary Cennerazzo gary.cennerazzo@parpharm.com
	Email Notification, Carolyn Hazard hazard.carrie@endo.com
	Email Notification, Par Notice Dept Par.noticeDept@parpharm.com
	Email Notification, Carol Purcell Purcell.Carol@endo.com
	Email Notification, Sandra Dilorio Dilorio.Sandra@endo.com

CT Corporation

Service of Process Transmittal

10/31/2019
CT Log Number 536547883

TO: Carol Purcell
Endo Pharmaceuticals Inc.
1400 Atwater Dr
Malvern, PA 19355-8701

RE: **Process Served in Delaware**

FOR: Endo Health Solutions Inc. (Domestic State: DE)

Email Notification, JULIANNE DECKER julianne.decker@parpharm.com

Email Notification, BETHANN MILES miles.bethann@endo.com

SIGNED: The Corporation Trust Company
ADDRESS: 1209 N Orange St
Wilmington, DE 19801-1120

For Questions: 866-401-8252
EastTeam2@wolterskluwer.com

SUMMONS	
First Judicial District Court Santa Fe County, New Mexico Court Address: P.O. Box 2268 Santa Fe, New Mexico 87504/87501 Court Telephone No.: 505-455-8250	Case Number: D-101-CV-2019-01809 Assigned Judge: **Bryan Biedscheid**
City of Santa Fe v. Cephalon, Inc., et al.	Defendant: **Endo Health Solutions, Inc.** c/o The Corporation Trust Company Corporation Trust Center 1209 Orange St. Wilmington, DE 19801

TO THE ABOVE NAMED DEFENDANT(S): Take notice that

1. A lawsuit has been filed against you. A copy of the lawsuit is attached. The Court issued this Summons.
2. You must respond to this lawsuit in writing. You must file your written response with the Court no later than thirty (30) days from the date you are served with this Summons. (The date you are considered served with the Summons is determined by Rule 1-004 NMRA) The Court's address is listed above.
3. You must file (in person or by mail) your written response with the Court. When you file your response, you must give or mail a copy to the person who signed the lawsuit.
4. If you do not respond in writing, the Court may enter judgment against you as requested in the lawsuit.
5. You are entitled to a jury trial in most types of lawsuits. To ask for a jury trial, you must request one in writing and pay a jury fee.
6. If you need an interpreter, you must ask for one in writing.
7. You may wish to consult a lawyer. You may contact the State Bar of New Mexico for help finding a lawyer at www.nmbar.org; 1-800-876-6657; or 1-505-797-6066.

Dated at Santa Fe, New Mexico, this 21st day of October, 2019.

KATHLEEN VIGIL
CLERK OF DISTRICT COURT

By: Victoria B. Neal
Deputy

FIRST JUDICIAL DISTRICT COURT STATE OF NEW MEXICO

Signature of Attorney for Plaintiff
Patrick W. Sullivan
100 Gold Avenue SW, Suite 1
Albuquerque, NM 87102
(505) 314-1414
(505) 314-1419
pat@salazar-sullivanlaw.com

THIS SUMMONS IS ISSUED PURSUANT TO RULE 1-004 OF THE NEW MEXICO RULES OF CIVIL PROCEDURE FOR DISTRICT COURTS.

RETURN[1]

STATE OF NEW MEXICO)
)ss
COUNTY OF _____)

I, being duly sworn, on oath, state that I am over the age of eighteen (18) years and not a party to this lawsuit, and that I served this summons in _____ county on the _____ day of _____, _____, by delivering a copy of this summons, with a copy of complaint attached, in the following manner:

(check one box and fill in appropriate blanks)

[ ] to the defendant _____ (*used when defendant accepts a copy of summons and complaint or refuses to accept the summons and complaint*)

[ ] to the defendant by [mail] [courier service] as provided by Rule 1-004 NMRA (*used when service is by mail or commercial courier service*).

After attempting to serve the summons and complaint on the defendant by personal service or by mail or commercial courier service, by delivering a copy of this summons, with a copy of complaint attached, in the following manner:

[ ] to _____, a person over fifteen (15) years of age and residing at the usual place of abode of defendant _____, (*used when the defendant is not presently at place of abode*) and by mailing by first class mail to the defendant at _____ (*insert defendant's last known mailing address*) a copy of the summons and complaint.

[ ] to _____, the person apparently in charge at the actual place of business or employment of the defendant and by mailing by first class mail to the defendant at _____ (*insert defendant's business address*) and by mailing the summons and complaint by first class mail to the defendant at _____ (*insert defendant's last known mailing address*).

[ ] to _____, an agent authorized to receive service of process for defendant _____.

[ ] to _____, [parent] [guardian] [custodian] [conservator] [guardian ad litem] of defendant _____ (*used when defendant is a minor or an incompetent person*).

[ ] to _____ (*name of person*), _____, (*title of person authorized to receive service. Use this alternative when the defendant is a corporation or an association subject to a suit under a common name, a land grant board of trustees, the State of New Mexico or any political subdivision*).

Fees: _____

_____
Signature of person making service

_____
Title (*if any*)

Subscribed and sworn to before me this _____ day of _____, _____[2]

_____
Judge, notary or other officer
authorized to administer oaths

_____
Official title

USE NOTE

1. Unless otherwise ordered by the court, this return is not to be filed with the court prior to service of the summons and complaint on the defendant.

2. If service is made by the sheriff or a deputy sheriff of a New Mexico county, the signature of the sheriff or deputy sheriff need not be notarized.

[Adopted effective August 1, 1988; as amended by Supreme Court Order 05-8300-01, effective March 1, 2005; by Supreme Court Order 07-8300-16, effective August 1, 2007; by Supreme Court Order No. 12-8300-026, effective for all cases filed or pending on or after January 7, 2013; as amended by Supreme Court Order No. 13-8300-022, effective for all cases pending or filed on or after December 31, 2013; as amended by Supreme Court Order No. 14-8300-017, effective for all cases pending or filed on or after December 31, 2014.]

FILED
1st JUDICIAL DISTRICT COURT
Santa Fe County
7/9/2019 3:39 PM
STEPHEN T. PACHECO
CLERK OF THE COURT
Victoria Neal

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

CITY OF SANTA FE

Plaintiff,

D-101-CV-2019-01809

Case assigned to Biedscheid, Bryan

v.

PURDUE PHARMA L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY;
PURDUE PHARMACEUTICALS L.P.;
CEPHALON, INC.;
TEVA PHARMACEUTICAL INDUSTRIES LTD;
TEVA PHARMACEUTICALS USA, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
CARDINAL HEALTH INC.;
ABBOTT LABORATORIES;
KNOLL PHARMACEUTICAL COMPANY;
ALLERGAN PLC f/k/a ACTAVIS PLC.;
ALLERGAN FINANCE LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.;
ALLERGAN SALES LLC; ALLERGAN USA INC.;
WATSON LABORATORIES, INC.;
WATSON PHARMA, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC., f/k/a ACTAVIS, INC.;
MCKESSON CORPORATION;
MCKESSON MEDICAL SURGICAL INC.;
CARDINAL HEALTH, INC.;
CARDINAL HEALTH 110 LLC;
CARDINAL HEALTH 200 LLC;
CARDINAL HEALTH 414 LLC;
AMERISOURCE BERGEN DRUG CORPORATION;
MALLINCKRODT LLC;
MALLINCKRODT PLC;
MALLINCKRODT BRAND PHARMACEUTICALS;

COVIDIEN PLC;
SPECGX LLC;
MCKESSON CORPORATION;
ABBVIE, INC.;
KNOLL PHARMACEUTICAL COMPANY;
CVS HEALTH;
WALGREENS BOOTS ALLIANCE INC, a/k/a WALGREEN CO.;
WAL-MART STORES, INC.;
JOHN BRAY-MORRIS, M.D.;
and NICOLE RENEE BRODERSON, N.P.

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND DEMAND FOR JURY TRIAL

I. PRELIMINARY STATEMENT

1. Plaintiff, the City of Santa Fe, New Mexico (the "City"), like many other communities across the United States, is struggling with an opioid crisis. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis began with a corporate business plan. It started with a decision by Purdue Pharma L.P., and its corporate family (collectively, "Purdue"), to promote opioids deceptively and illegally to significantly increase sales and generate billions of dollars in revenue for Purdue's private owners, the Sackler family. Unfortunately, Purdue's strategies were quickly adopted by other pharmaceutical manufacturers: Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Mallinckrodt PLC; Mallinckrodt Brand Pharmaceutical, Inc.; Mallinckrodt LLC; and SpecGx LLC (collectively with Purdue, "Manufacturer Defendants"), all of whom, used misrepresentations regarding the risks and

benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[1]

2. In addition, the Manufacturer Defendants, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., and CVS Health, (collectively, "Distributor Defendants") failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders (e.g., orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency).

3. Further, Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., and CVS Health held special obligations under the law as registered retail pharmacies (collectively the "Pharmacy Defendants"). On thousands of occasions, the Pharmacy Defendants ignored unresolvable red flags and filled prescriptions outside the usual course of practice and for other than a legitimate medical purpose, leading directly to the diversion of millions of pills of highly abused opioid controlled substances.

4. Defendant John Bray-Morris, M.D. ("Dr. Bray-Morris") is a doctor operating a medical practice in the City. Dr. Bray-Morris recently agreed to voluntarily surrender his license to practice medicine in the State of New Mexico based upon his prescribing of dangerous opioid controlled substances in violation of New Mexico law. Defendant Nicole Renee Broderson, N.P. ("Nurse Broderson") is a nurse practitioner working in the City. She was convicted in 2017 of unlawfully dispensing dangerous controlled opioid substances. As a direct consequence of the actions of practitioners, including Dr. Bray-Morris and Nurse Broderson, the rampant use,

[1] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

overuse, and abuse of opioids has overwhelmed much of New Mexico, including the City and its residents.

5. The City brings this action to redress Defendants' campaign of unfairly, deceptively, and fraudulently marketing, promoting, and distributing opioids.

6. Manufacturer Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

7. Distributor Defendants McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., and CVS Health distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the United States and in and around the City.

8. Pharmacy Defendants review prescriptions issued from licensed and DEA-registered practitioners, such as physicians, and ultimately choose whether or not to fill the issued prescription for the end-user customer. Pharmacy Defendants are the final line of defense in preventing the diversion of opioid medications, such as those listed above, for improper use, abuse, or illicit sale.

9. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. Opioids can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience severe and often prolonged withdrawal symptoms. When using opioids

continuously, patients grow tolerant to their analgesic effects (i.e., to relief of pain) — requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

10. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain — where brief use limited the need for escalating doses and the risk of addiction — or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

11. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, joined by Teva, Janssen, Endo, and Mallinckrodt began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, these Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use. From the day they made the opioids to the day the medicines were consumed in our communities, including in and around the City, the Manufacturer Defendants had control over the information that they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing more and more of their products by arguing, among other things, that they fail to meet the standard of care if their patients continue to complain of pain, the Manufacturer Defendants created a population of addicted patients, including in the City, who sought opioids at never-before-seen rates.

12. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, pharmacies, and individual

defendants (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids and against diversion, and who instead have actively sought to evade such controls and ignore red flags of potential diversion. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report or take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

13. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than in 1999.

14. As a direct and foreseeable result of Defendants' conduct, cities and counties across the United States, including the City, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[2] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who can no longer legally acquire or simply cannot afford prescription opioids.

15. This explosion in opioid use and the concurrent explosion in Defendants' profits have come at the expense of patients and have caused ongoing harm and damages to the City. As

[2] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

the then CDC director concluded in 2016: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.[3]

16. A substantial amount of the costs associated with opioid use and opioid abuse disorder is borne by government entities. The necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care, among others.

17. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis. Within the next hour, five Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers and distributors will earn millions from the sale of opioids.

18. Accordingly, the City brings this action to hold Defendants accountable for their conduct and to seek damages, abatement, and any other injunctive and equitable relief within this Court's powers to redress and halt Defendants' unfair, deceptive, and unlawful practices.

II. PARTIES

A. Plaintiff

19. The City is an incorporated municipality in New Mexico with powers conferred upon it by, *inter alia*, Article 18 of the Municipal Code. Pursuant to N.M. Stat. Ann. § 3-18-1, the City has the capacity to sue.

20. The City is located in Santa Fe County, New Mexico, and has a population of 83,776. The City provides many services for its residents, including public health, public

[3] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

assistance, law enforcement, emergency care, and services for families and children. For its employees, the City also funds its own health insurance and workers' compensation programs.

21. The City brings this action on its own behalf and in the public interest.

B. Defendants

i. Manufacturer Defendants

22. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Together, these entities are referred to herein as "Purdue." In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids.

23. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in the County.[4] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

24. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States, including in and around the City. Teva USA also sells generic opioids throughout the United States and in and around the City. In August 2016,

[4] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

Teva Pharmaceutical Industries Ltd., which is based in Israel and is Teva USA's parent company, acquired Allergan PLC, including the generic opioid business that Allergan had previously operated. These parties are collectively referred to herein as "Teva."

25. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the United States and in the City. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, Gabitril and Provigil, and agreed to pay $425 million.

26. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit.

27. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. One code of conduct on Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

28. Similarly, the "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

29. J&J also asserts control over Janssen through its management team. According to Janssen's website, the "leadership team that guides Janssen" contains several J&J executives.[5]

30. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and

[5] Members of Janssen's "leadership team" include Joaquin Duato, Vice Chairman of the Executive Committee, Johnson & Johnson; Paul Stoffels, M.D. Vice Chairman of the Executive Committee, Chief Scientific Officer, Johnson & Johnson; Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson; and, Scott White, Company Group Chairman, North American Pharmaceuticals, Johnson & Johnson. *See* https://www.janssen.com/about/our-leadership (last visited on April 24, 2019).

maximize the use of opioids. In addition, J&J made payments to Front Groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[6] Janssen and J&J are collectively referred to herein as "Janssen."

31. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and in and around the City, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

32. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in and around the City. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and in and around the City, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the

[6] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, n. 23 ("Payments from Janssen include payments from Johnson & Johnson, Health Care Systems, Inc.").

company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as an abuse-deterrent.

34. Mallinckrodt, PLC, is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, PLC. Prior to June 28, 2013 Mallinckrodt, LLC, was a wholly-owned subsidiary of Covidien PLC. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt PLC. Defendant SpecGx, LLC, is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt PLC. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt, LLC. Mallinckrodt, PLC, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals, and SpecGx, LLC, are referred to as "Mallinckrodt."

35. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

36. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. In 2015, Mallinckrodt estimated, based on IMS Health data, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[7] In 2017, Mallinckrodt paid a $35 million fine to the Department of Justice for its failure to report suspicious orders of its opioids.[8]

37. Collectively, Purdue, Teva, Janssen, Endo, and Mallinckrodt are referred to herein as "Manufacturer Defendants."

iii. Distributor Defendants

38. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the United States, including in the City. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

39. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including in and around the City. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

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[7] https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm.

[8] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

40. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including in the City. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

41. Cardinal, McKesson and AmerisourceBergen are, at times, collectively referred to herein as "The Big Three."

42. Walgreens Boots Alliance d/b/a Walgreen Co. ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in New Mexico and throughout the United States, including in the City. Walgreens is headquartered in Deerfield, Illinois, and has distribution centers across the United States which distribute medications, including opioids, to various states, including New Mexico. Walgreens is registered to do business in New Mexico under the name Walgreen Co. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States and in the City. According to its website, Walgreens operates 9,560 retail stores with pharmacies, including 23 retail locations in the state of New Mexico, four of which operate within the City.

43. Wal-Mart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Arkansas. At all relevant times, Wal-Mart has sold and continues to sell prescription opioids at locations in and in close proximity to the City. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States and in the City. According to its website, Wal-Mart operates 3,646 retail stores with pharmacies, including 121 retail locations in the state of New Mexico, three of which operate within the City.

CVS Health ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. During all relevant times, CVS Health has sold and continues to sell prescription opioids in and in close proximity to the City. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States and in and around the City.

46. Cardinal, McKesson, AmerisourceBergen, Walgreens, Wal-Mart, and CVS are at times collectively referred to herein as "Distributor Defendants."

47. The Distributor Defendants dominate the wholesale distribution market, including in the City. In order to increase their revenue, increase their profits, and grow their share of the prescription painkiller market, each of the Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their fundamental duty under New Mexico statutes and New Mexico common law, to detect, report, and refuse to ship suspicious orders of opioids in order to prevent diversion of these dangerous drugs for non-medical purposes. Each has been cited and fined by the DEA and/or DOJ for failing to maintain effective controls against diversion. This unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing the City.

iv. Pharmacy Defendants

48. Additionally, Walgreens, Wal-Mart, and CVS are registered retail pharmacies in the state of New Mexico and are at times collectively referred to herein as "Pharmacy Defendants."

49. The Pharmacy Defendants represent 46.6 %, or nearly half of all prescription drug sales in the United States. In order to avail themselves of rebate programs with pharmaceutical distributors, and thus maximize their profits, the Pharmacy Defendants incentivized employees with volume-based bonuses for filling prescriptions for opioid controlled substances. In lieu of

upholding their obligations under the law, Pharmacy Defendants instead consistently chose to ignore unresolvable red flags of diversion, and thus filled prescriptions without ensuring the prescription had been issued for a legitimate medical purpose in the course of usual medical practice.

50. Dr. Bray-Morris operated his medical practice out of the City. Dr. Bray-Morris prescribed opioid controlled substances to patients in and around the City for illegitimate and illicit purposes, include the abuse and diversion of those opioid controlled substances, in derogation of his duties under New Mexico law and under the New Mexico Medical Board.

51. Nurse Broderson was employed as a nurse practitioner working in the City, New Mexico. Nurse Broderson prescribed opioid controlled substances to patients in and around the City for illegitimate and illicit purposes, include the abuse and diversion of those opioid controlled substances, in derogation of her duties under New Mexico law and under the New Mexico Board of Nursing.

III. JURISDICTION AND VENUE

52. The venue for this claim is proper in the First Judicial District Court for Santa Fe County.

53. Venue as to each Defendant is proper in this Court because each of the Defendants carry on regular business in the City and/or the causes of action alleged in this Complaint arose in the City.

54. This Court has subject matter jurisdiction over this action.

55. This Court has personal jurisdiction over Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants pursuant to NMSA 1978, Section 38-1-16 because they transact business in the state of New Mexico, and have committed a tortious act within this State.

The Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants have systematic and continuous contacts with the State of New Mexico.

56. This Court has personal jurisdiction over Defendant Dr. Bray-Morris because he is a resident of the City and operates his medical practice within the City.

57. This Court has personal jurisdiction over Defendant Nurse Broderson because she is a resident of the City and operates her medical practice within the City.

58. The City does not allege any federal cause of action, and to the extent that any pleading allegedly can be interpreted as stating any claim arising under federal law, any and all such federal claims are expressly disavowed. No federal question, substantial or otherwise, arises from the City's pleadings or is stated in said pleadings. Every claim and pleading by the City in this case can be adjudicated without resolving any federal question; therefore, federal questions are not raised and are certainly not necessarily resolved. Moreover, even assuming there is a federal question, which is denied, no such federal question is substantial to the federal system as a whole. *See Gunn v. Minton*, 568 U.S. 251 (2013). To the extent federal enforcement actions are discussed in this complaint, these pleadings do not state any federal claim or raise any federal question but rather are factual allegations showing Defendants' *mens rea* and the course of Defendants' malfeasance as a factual matter. No federal question is substantial, is raised, or is necessarily adjudicated here because New Mexico statutory and regulatory requirements mirror federal duties with regard to controlled substances, and the City is exclusively relying on the state statutes, the state regulations, and state common law rather than on any federal law, regulation, or standard. The City makes no claim, and expressly disavows any alleged claim, against or directed to the United States or any agency thereof or any officer (or any person acting under that officer) of the United States or any agency thereof, in an official or individual

capacity, for or relating to any act under color of such office; including without limitation, the City denies seeking, and expressly disavows, any recovery arising from McKesson Corporation's federal contract to supply prescription medication. *See* 28 U.S.C. § 1442. The statements in this paragraph are controlling notwithstanding anything alleged to the contrary.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

60. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Manufacturer Defendants have sought to successfully turn that consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

61. Through marketing that was as pervasive as it was deceptive, Manufacturer Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven, undermining general warnings in labels and elsewhere. Purdue's sales representatives, in particular, promoted the concept that pain was undertreated, that opioids could not be abused, that the rate of addiction to opioids was less than 1%, that "old views" of opioid addiction were untrue, and that "appropriate patients" would not become addicted. These themes were repeated by sales representatives from other Manufacturer Defendants.

62. The Manufacturer Defendants blanketed the medical community with their misleading and deceptive misinformation campaign to change the narrative regarding the appropriate use of opioid medications and increase their profits. They enlisted trusted doctors, professional associations, and patient groups to disseminate their misrepresentations overstating

the benefits of opioid use for chronic pain conditions and downplaying the risks of such use. As discussed more fully below, these doctors and groups appeared to be independent, but were funded and controlled by the Manufacturer Defendants to distort the public's and medical communities' perception of the risks, benefits, efficacy, and superiority of opioids to treat chronic pain. Misleading and deceptive messages were disseminated through seminars, physician Continuing Medical Education programs, speaker programs, websites, patient guides, and "scientific" and other publications given to doctors and stacked in patient waiting rooms.

63. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturer Defendants not only deceptively marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants),[9] who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' misleading marketing claims.

64. Manufacturer Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

[9] For example, in 2013, Purdue sought to identify Key Opinion Leaders ("KOLs") to reach non-physician prescribers, including for a program to educate nurses about opioids. By 2015, nurse practitioners and physician assistants were responsible for over 800 million prescriptions and constituted Purdue's largest growth area.

A. Manufacturer Defendants Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

65. Manufacturer Defendants, rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. These visits frequently coincide with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Purdue's former Vice President of Marketing, Russ Gasdia, acknowledged the utility of a Purdue sales representative as "someone [prescribers] can look to for the information they need to make prescribing decisions." Upon information and belief, all of the Manufacturer Defendants had sales representatives who visited prescribers in the City.

66. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report that noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[10] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

67. To ensure that sales representatives delivered the desired messages to prescribers, Manufacturer Defendants directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each of their visits. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the companies' marketing and

[10] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization*.

compliance departments. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, upon information and belief,[11] their sales forces in New Mexico and the City carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the United States.

68. Manufacturer Defendants were aware of the strength of in-person marketing. The effects of sales calls on prescribers' behavior are well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[12] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization.[13] An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.[14]

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[11] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Santa Fe in the same manner as elsewhere.

[12] Ian Larkin *et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. AM. MED. ASS'N 1785 (2017).

[13] Berdent ER, *et al., Information, Marketing and Pricing in the US Antiulcer Drug Market*, 85 AMER. ECON. REV. 101 (1995).

[14] Wazana A., *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*,

69. Manufacturer Defendants also used "key opinion leaders" ("KOLs") — experts in the field who were especially influential because of their reputations and seeming objectivity — to deliver paid talks and continuing medical education programs ("CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Manufacturer Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the Defendants' messages regarding the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[15]

70. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Manufacturer Defendants exerted influence over these groups by providing major funding directly to them, as well. These "Front Groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain by overstating their benefits, and understating their risks. In many instances, Manufacturer Defendants distributed these publications to prescribers or posted them on their websites.

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283 JAMA 378 (2000).

[15] Catan, Thomas, and Perez Evan, "A Pain-Drug Champion Has Second Thoughts," The Wall Street Journal, December 17, 2017, available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

71. The FDA does not regulate all of the conduct in which the Manufacturer Defendants engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue and, upon information and belief, the other Manufacturer Defendants marketed their drugs. The FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate the marketing messages or scripts relied on by Manufacturer Defendants' sales representatives or marketing funneled through third-parties. Upon information and belief, all of the messages described below were disseminated to prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources, including in and around the City.

i. Minimizing or mischaracterizing the risk of addiction

72. To convince prescribers and patients that opioids should be widely prescribed for long term use of chronic pain conditions and increase the market for and sales of opioids, Manufacturer Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted; (2) patients at greatest risk of addiction could be identified, (3) all other patients could safely be prescribed opioids, and (4) even high-risk patients could be prescribed opioids if closely managed.

73. Upon information and belief, sales representatives regularly omitted from their sales conversations with prescribers in and around the City any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

74. Manufacturer Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to these Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. Manufacturer Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. One former Purdue sales representative in another region confirmed Purdue's message that opioids were appropriate and safely prescribed to legitimate patients with actual pain; upon information and belief, the same message was delivered to prescribers in and around the City. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction.

75. In addition, upon information and belief, Manufacturer Defendants' sales representatives also failed to disclose to prescribers in and around the City the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

76. Manufacturer Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa —under the heading "Indications of Possible Drug Abuse." Purdue knew that opioid addicts who resort to these extremes are uncommon; they far more typically become dependent and addicted through prescribed oral use. According to

briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time.

77. These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, to prescribers in and around the City.

78. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"). Purdue was APF's second-biggest donor. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill.

79. *A Policymaker's Guide to Understanding Pain & Its Management*, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction. Purdue provided funding in the form of a $26,000 grant to APF and closely collaborated with APF in creating *A Policymaker's Guide*. On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*.

80. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain* that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. Although it included the Purdue

copyright at the bottom of each page, the site did not refer to any specific Purdue products and cultivated the "impression that it [was] neutral and unbiased."[16]

81. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013 — a fact notably omitted from the site.

82. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

83. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

84. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

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[16] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151 (August 19, 2015).

85. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

86. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[17]

87. Among its content, the website contained a handout titled *Oxycodone Safety for Patients,* which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[18] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

88. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and

[17] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php.

[18] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!* The false claims and misrepresentations in this book include the following statements:

a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."

c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."

d. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

e. "[I]n our experience, the issue of tolerance is overblown."

f. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."

g. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."

h. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

i. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

This book is still available online.

89. Manufacturer Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as

many as 30-40%, of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk [] of ... addiction" — "even at recommended doses" — of all opioids.[19] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[20] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[21] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

90. Furthermore, to the extent Defendants' labels mentioned the risks of addiction or abuse, Defendants' misleading and deceptive marketing minimized and trivialized these risks, reassuring physicians that they could prescribe opioids for long-term use because their patients were unlikely to become addicted.

ii. Manufacturer Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

91. Manufacturer Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented by Manufacturer Defendants to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids

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[19] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[20] CDC Guideline at 2.

[21] *Id.* at 21.

or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. By disseminating misleading information regarding pseudoaddiction, Defendants acted with the sole purpose of increasing their profits at the expense of patients.

92. Purdue, through its unbranded imprint *Partners Against Pain*[22], promoted pseudoaddiction through at least 2013 on its website.

93. The Federation of State Medical Boards ("FSMB"), a national organization representing state medical boards, including the New Mexico Medical Board, finances opioid- and pain-specific programs through grants from Manufacturer Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

94. The Manufacturer Defendants sponsored the publication of *Responsible Opioid Prescribing*. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in and around the City.

95. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-*

[22] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

96. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

97. Manufacturer Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturer Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

98. The FAQs section of pain-topics.org, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'" [23]

99. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-

[23] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance.

term use,"[24] and that physicians should "reassess [] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[25]

iii. Overstating the efficacy of screening tools

100. Manufacturer Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturer Defendants undermined general concerns or warnings regarding addiction in drug labels and elsewhere by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

101. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

102. Upon information and belief, these Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors in and around the City.

[24] CDC Guideline at 13.

[25] *Id.* at 25.

103. On information and belief, Purdue sales representatives in and around the City also shared the *Partners Against Pain* "Pain Management Kit," which contained several "drug abuse screening tools." These included the "Opioid Risk Tool," which is a five question, one-minute screening tool that relies on patient self-reporting to identify whether there is a personal history of substance abuse, sexual abuse, or "psychological disease," ignoring the sensitivity of the topic and the nature of addiction, which make it unlikely that many patients can be counted on to share this information.

104. Manufacturer Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to prescribers in and around the City.

105. For example, Purdue sponsored a 2011 CME program titled *Managing Patients' Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths."

106. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, high-risk patients showing signs of addictive behavior could be treated with opioids.

107. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number

of talks—with very different messages from non-Purdue talks—at each CPDD conference. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the addiction crisis, and that once those patients are identified doctors can safely prescribe opioids to others without causing addiction. Hundreds of addiction treatment specialists from across the United States and, upon information and belief, prescribers from in and around the City, attended these conferences.

108. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

109. A 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

110. Manufacturer Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As these Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

111. Further, the 2016 CDC Guideline confirms the falsity of Manufacturer Defendants' claims about the utility of patient screening and management strategies in managing

addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools or patient contracts — "for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[26]

B. Manufacturer Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use in Order to Increase their Profits

i. Mischaracterizing the benefits and evidence for long-term use

112. To convince prescribers and patients that opioids should be used to treat chronic pain to increase the number of opioid prescriptions and their profits, Manufacturer Defendants had to persuade the medical community of a significant upside to long-term opioid use. Assessing existing evidence, the 2016 CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[27] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[28] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[29] The FDA also

[26] CDC Guideline at 28 (emphasis added).

[27] *Id.* at 10.

[28] *Id.* at 9.

[29] Letter from Janet Woodcock, M.D., Dir., Center for Drug Eval. and Research, to

determined that opioid use disorder risk and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

113. Upon information and belief, Manufacturer Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

114. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Manufacturer Defendants. Upon information and belief, Manufacturer Defendants exercised considerable influence over the organizations' work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

115. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturer Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain,

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Andrew Kolodny, M.D. (Sept. 10, 2013).

but who frequently treat patients who suffer from chronic pain, such as the elderly. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

116. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

117. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

118. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

119. Manufacturer Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions, and pose little risk to patients. One study asserts that OxyContin is safe and effective for the chronic pain condition

osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results… should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[30] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[31] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

120. Teva deceptively marketed its opioids, Actiq and Fentora, for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

121. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the

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[30] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[31] *Id.*

high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

122. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[32] by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

123. For example, Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

124. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

125. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology

[32] Pharmaceutical detailing is a one-on-one marketing technique utilized by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain. The FDA does not regulate or approve journal publications sponsored by drug manufacturers, such as the Special Report.

126. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

127. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

ii. Overstating opioids' effect on patients' function and quality of life

128. Upon information and belief, Manufacturer Defendants also claimed to doctors in and around the City — without evidence — that long-term opioid use would help patients resume their lives and jobs.

129. Manufacturer Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in the City, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain

patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

130. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

131. Defendant Mallinckrodt's website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[33] Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009)—which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

c. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

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[33] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

d. Purdue and Teva sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

e. Endo's NIPC website, painknowledge.com, claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

f. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

132. Likewise, Manufacturer Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

133. One pain specialist observed, "Opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[34] Studies of patients with lower back pain and

[34] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009),

migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[35] Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.[36]

134. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[37] The FDA and other federal agencies have made this clear for years. [38] The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[39] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are

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http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[35] *Id.*

[36] Jeffrey A. White, et al., The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[37] CDC Guidelines. at 20.

[38] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[39] CDC Guideline at 2.

uncertain, risks associated with long-term opioid use are clearer and significant."[40] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[41]

135. In materials Manufacturer Defendants produced, sponsored, or controlled, Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

iii. Omitting or mischaracterizing adverse effects of opioids

136. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturer Defendants routinely ignored the risks of hyperalgesia, a known serious risk associated with chronic opioid analgesic therapy, in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

137. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have

[40] *Id.* at 18.

[41] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

"no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[42] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

138. Purdue also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

139. Purdue sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

140. Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See, e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (stating that NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).

[42] The higher figure reflects deaths from all causes.

141. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[43] Again, Manufacturer Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions resulting from a doctor visit increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions per visit fell from 38% to 29% .[44] Another study of an estimated 440 million visits for back pain over a period from 1999 to 2010 found that the use of NSAIDs fell from 36.9% to 24.5% of doctor visits resulting in prescriptions, while use of narcotics increased from 19.3% to 29.1.%.[45] The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.[46]

C. Manufacturer Defendants Continued to Tell Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

142. Manufacturer Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribing opioids for more frequent dosing.

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[43] Meredith Noble M, *et al.*, *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

[44] John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

[45] *Id.*

[46] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.

143. Purdue-sponsored publications and CMEs available, upon information and belief, in and around the City, also misleadingly suggested that higher opioid doses carried no added risk.

144. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

145. *A Policymaker's Guide*, the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary" but did not disclose the risks from high dose opioids.

146. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but did not disclose risks from opioids at high doses. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

147. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased... You won't 'run out' of pain relief."

148. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

149. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose, even where opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[47] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[48]

D. Purdue Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief When Purdue Knew That, For Many Patients, It Did Not

150. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

151. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below. Purdue conveyed

[47] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[48] CDC Guideline at 16.

to prescribers that the solution to end-of-dose failure is not more frequent dosing but higher doses—which pose greater risks.

152. OxyContin has been FDA-approved for twice-daily — "Q12" — dosing frequency since its debut in 1996. It was Purdue's decision to submit OxyContin for approval with 12-hour rather than 8-hour dosing. Under FDA guidelines for establishing dosing, Purdue merely had to show that OxyContin lasted for 12 hours for at least half of patients, and Purdue submitted a single study that cleared that bar.

153. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end-of-dose failure"—i.e., little or no pain relief at the end of the dosing period.

154. Moreover, Purdue itself long has known, dating to its development of OxyContin that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers — "rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.[49]

[49] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*,"

155. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience distressing psychological and physical withdrawal symptoms, followed by a euphoric rush with their next dose — a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[50] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

156. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (e.g., every 8 hours) because 12-hour dosing was "a significant competitive advantage," among other reasons.[51] Purdue also falsely promoted OxyContin as providing "steady state" relief, less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse—a misrepresentation made upon information and belief, in and around the City.

157. Without appropriate caveats, promotion of 12-hour dosing by itself is misleading because it implies that the pain relief supplied by each dose lasts 12 hours, which Purdue knew to be untrue for many, if not most, patients. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing, to disclose to prescribers what it knew about OxyContin's actual duration, and not to promote more

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Los Angeles Times, May 5, 2016, http://www.latimes.com/projects/oxycontin-part1/.

[50] *Id.*

[51] *Id.*; http://documents.latimes.com/purdue-response-fda-2004/.

dangerous higher dosing, rather than increased frequency of use, regardless of any marketing advantage.

158. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 milligrams of morphine equivalent that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[52]

E. Purdue and Endo Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

159. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids— thereby further exacerbating the opioid epidemic in the City and elsewhere.

i. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

[52] CDC Guideline at 16.

160. Reformulated, ADF OxyContin was approved by the FDA in April 2010. However, the FDA noted that "the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse)." It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in the label. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties.

161. It is unlikely to be a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

162. Upon information and belief, Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis to prescribers in and around the City.

163. Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue detailers:

a. claimed that Purdue's ADF opioids *prevent* tampering and that its ADF products could not be crushed or snorted.

b. claimed that Purdue's ADF opioids *reduce* opioid abuse and diversion.

c. asserted or suggested that Purdue's ADF opioids are "safer" than other opioids.

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

164. These statements and omissions by Purdue are false and misleading and are inconsistent with the FDA-approved labels for Purdue's ADF opioids—which indicate that abusers seek them because of their high likeability when snorted, that their abuse deterrent properties can be defeated, and that they can be abused orally notwithstanding their abuse-deterrent properties, and which do *not* indicate that ADF opioids prevent or reduce abuse, misuse, or diversion.

165. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[53] and is still regularly tampered with and abused. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, also report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected[54].

166. Further, *one-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin.

167. A 2013 article, presented by Purdue employees based on the review of data from poison control centers, ignored important negative findings while concluding that ADF OxyContin can reduce abuse. The study reveals that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful

[53] *In re OxyContin*, 1:04-md-01603-SHS, Docket No 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

[54] PMRS Citizens Petition.

exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article emphasized the advantages and ignored disadvantages of ADF OxyContin.

168. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[55] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death." [56]

169. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff were to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[57] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

170. Yet despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the

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[55] CDC Guideline at 22. (emphasis added).

[56] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[57] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

evidence does not show that Purdue's ADF opioids are being abused in large numbers.[58]

ii. Endo's deceptive marketing of reformulated Opana ER

171. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent formulations, also made abuse deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

172. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

173. In August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of

[58] Jacobs, Harrison, There is a Big Problem With the Government's Plan to Stop the Drug-Overdose Epidemic, Business Insider, March 16, 2016, available at https://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3.

original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

174. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[59] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[60]

175. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[61]

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[59] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[60] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[61] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al..*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

176. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

177. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"), which can cause kidney failure.[62] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

178. Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in New Mexico and in and around the City that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was

[62] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

easier to abuse intravenously and, if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

179. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

180. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[63] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[64] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[65]

181. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in

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[63] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[64] *Id.*

[65] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally.

182. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

G. All Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Terminate Suspicious Orders

208. The Manufacturer Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to terminate orders that they knew or should have known were suspicious breached both their statutory and common law duties.

209. For over a decade, as the Manufacturer Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

i. All Defendants Have a Duty to Report Suspicious Orders and Terminate those Orders Unless Due Diligence Disproves Their Suspicions.

210. Statutes, regulations, and the common law impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

211. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By supplying the area in and around the City with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm to the City. As the supply of opioids and the evidence of addiction to and abuse of these drugs grew, manufacturers, distributors, and pharmacies were again reminded of both the nature and harms of opioid exposure and use.

212. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion of prescription opioids, to speak accurately and truthfully.

213. Third, Defendants violated their statutory obligations under New Mexico law. As manufacturers and wholesale drug distributors of controlled substances, Defendants were required to register with the DEA. *See* 16.19.8.23(A)(4) and 24(C) NMAC. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 16.19.20.48(A) NMAC. This same standard is promulgated in the criminal statues, specifically New Mexico's Controlled Substances Act. NMSA 1978, § 30-3l-13(A)(l) (providing that "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels" is a mandatory factor in board registration).

214. The New Mexico Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations and impose registration duties upon manufacturers and distributors of controlled substances. *E.g.,* 16.19.8.13(1) NMAC; NMSA 1978, §§ 30-31- 13(C), 30-31-16(A). The State's regulations are intended to conform to federal regulations barring any impracticality. See NMSA 1978, § 26-1-18(A) (2005) ("The board shall conform the regulations promulgated under the New Mexico Drug, Device and Cosmetic Act, insofar as practical, with regulations promulgated under the federal act as defined in Section 26- 1-2 NMSA 1978.").

215. All Defendants must comply with statutory and regulatory duties to guard against diversion of highly addictive controlled substances into illicit channels. *See generally,* 16.19.6 NMAC (incorporating by reference federal law in pharmacy regulation); 16.19.20 NMAC (incorporating by reference federal law in controlled substances regulation).

216. The New Mexico Board of Pharmacy governs for the licensing of wholesale drug distributors in this State. NMSA 1978, § 61-11-6(A)(6) (2005). Under New Mexico regulations, "[w]holesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs." 16.19.8.13(F)(1) NMAC. "Wholesale drug distributors that deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations." 16.19.8.13(1)(2) NMAC.

217. Of particular import here, New Mexico regulations require that any diversion of a prescription drug be reported to the New Mexico Pharmacy Board, the FDA, and where applicable, to the DEA 16.19.8.13(F)(5) NMAC ("Wholesale distributors shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and FDA and where applicable, to the DEA"). The same duty exists under federal regulations,

which are incorporated by reference. See NMSA 1978, §§ 30-3l-13(C), 30-3l-16(A); 16.19.8.13(1) NMAC (incorporating federal regulation by reference); 21 C.F.R. § 1301.74(b).[66] It is a crime to intentionally fail to furnish notifications required by the Controlled Substances Act and to intentionally omit any material information from any document required to be filed, or any record required to be kept, by the Act. NMSA 1978, § 30-3 l-24(A)(3).

218. Defendants have violated their duties under the New Mexico Controlled Substances Act and the New Mexico Administrative Code. See NMSA 1978, §§ 30-31-20, 30-31-24, 30-31- 25; 16.19.8 NMAC; 16.19.20 NMAC.

219. Opioids are Schedule II controlled substances. NMSA 1978, § 30-31-7(A). As such, opioids are defined as substances that pose a high potential for abuse that may lead to severe dependence. NMSA 1978, § 30-3 l-5(B).

220. Defendants violated their duties as licensed wholesale distributors by selling huge quantities of opioids that were diverted from their lawful, medical purpose, thus causing an opioid and heroin addiction and overdose epidemic in this City.

221. As the DEA advised Defendants in a letter to them dated September 27, 2006, Defendants, as wholesale distributors, are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

[66] To be crystal clear, the City cites federal statutes and federal regulations in this complaint to state the duty owed under New Mexico tort law, not to allege an independent federal cause of action or substantial federal question, both of which are expressly and unequivocally denied.

This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[67]

222. Defendants violated New Mexico law when they violated a federal regulation that is incorporated into New Mexico law. 16.19.8.13(1) NMAC (which requires compliance with *inter alia* 21 C.F.R. § 1301.74(b)); 16.19.20.42 (requiring compliance with Part 1306.08 of the Code of Federal Regulations); 16.19.20.49 NMAC ("Security requirements which meet the federal DEA provision shall be deemed adequate under New Mexico Controlled Substances Act."); *see also* NMSA 1978, § 26-l-18(A). Defendants thereby had a duty to disclose suspicious orders:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).[68] New Mexico law dictates the source of the duties owed. Therefore, even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is New Mexico law, and not any federal authority, that informs the existence of a duty.

223. "Suspicious orders" include orders of an unusual size, orders deviating

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[67] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enft Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."),*filed in Cardinal Health, Inc. v. Holder*, No. l:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

[68] Once again, the City cites federal regulations in this complaint to state the duty owed under New Mexico law, not to allege an independent federal cause of action or substantial federal question, both of which are expressly and unequivocally denied.

substantially from a normal pattern and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

224. Thus, New Mexico regulations mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the requisite authority. Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert Defendants to potential problems.

225. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor who observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply – can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual, given the customer's history or its comparison to other customers in the area.

226. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under state law with respect to control of the supply chain of opioids. They must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

227. New Mexico statutes, regulations, and common law reflect a minimum standard of conduct and care that reasonably prudent manufacturers and distributors are required to meet. Together, these laws and industry guidelines make clear that Defendants must possess, and are obligated to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

228. Further, these laws and industry standards make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

229. The FTC has recognized the unique role of Defendants McKesson, Cardinal, and AmerisourceBergen (the "Big Three"). Since their inception, the Big Three have continued to

integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, the Big Three also offer their pharmacy, or dispensing, customers a broad range of added services. For example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory-carrying costs. The Big Three are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.[69] As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the range of additional services they offer, the Big Three have a unique insight into the ordering patterns and activities of their dispensing customers.

230. Like the Big Three, Walgreens, Wal-Mart, and CVS are uniquely positioned to know the ordering patterns and activities of their dispensing customers due to their roles as both distributors and national retail pharmacies. As national retail pharmacies, Walgreens, Wal-Mart, and CVS have vertically integrated models, which place them in a unique role, as they have both specific obligations under the CSA and a particular ability to spot, report, and stop filling suspicious orders. National retail pharmacies, like other distributors, must become registrants to legally distribute and/or dispense controlled substances. *E.g.*, 21 C.F.R. § 1301.11.[70] Pharmacy registrants, inasmuch as they act as distributors, are required to "provide effective controls and

[69] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.).

[70] Here and elsewhere, all federal cites are only to duties incorporated into New Mexico law, and any independent federal cause of action or substantial federal question is unequivocally and expressly disavowed.

procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a).[71]

231. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a).[72] Because pharmacies themselves are registrants, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

232. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify red flags of diversion and what to do when such red flags have been identified.

233. Specifically, DEA has identified several types of "unresolvable red flags" which, when presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include:

a. A prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances;

b. Multiple prescriptions presented by the same practitioner to patients form the same address, prescribing the same controlled substances in each presented prescription;

c. A high volume of patients presenting prescriptions and paying with cash;

[71] Here and elsewhere, all federal cites are only to duties incorporated into New Mexico law, and any independent federal cause of action or substantial federal question is unequivocally and expressly disavowed.

[72] Here and elsewhere, all federal cites are only to duties incorporated into New Mexico law, and any independent federal cause of action or substantial federal question is unequivocally and expressly disavowed.

d. A prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

234. When a pharmacist identifies any such red flags of diversion, the pharmacist must not fill the prescription. Filling a prescription without resolving such red flags is a violation of a pharmacist's legal duty and corresponding responsibility not to fill a prescription outside the usual course of practice and for other than a legitimate medical purpose.

235. New Mexico prescribing laws forbid a pharmacist from "[d]ispensing a prescription for a dangerous drug without an established practitioner-patient relationship." 16.19.4.9(C)(18) NMAC. Further, a pharmacist is required to perform a prospective drug review of every prescription issued and, prior to dispensing, "a pharmacist shall review the patient profile for the purpose of identifying" clinical abuse/misuse; therapeutic duplication; drug-drug interactions; incorrect drug dosage; and incorrect duration of drug treatment. *See* 16.19.4.16(D)(1) NMAC.

236. Upon identifying any of the enumerated concerns, "a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing a controlled substance prescription monitoring report or another states' reports if applicable and available, and consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem." 16.19.4.16(D)(2) NMAC.

237. Additional types of resolvable red flags of diversion include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions

which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible as compared to most written prescriptions; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

238. Other signs of diversion can be observed through data that is gathered, consolidated, and analyzed directly by Pharmacy Defendants. That data allows national retail pharmacies, like Pharmacy Defendants, to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[73] The majority of pharmacies sell these records.[74]

239. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

240. Manufacturer Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors'

[73] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[74] *Id.* at 389.

offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Manufacturer Defendants to observe the signs of suspicious prescribing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing that would have alerted them to suspicious prescribing. These information points gave Manufacturer Defendants insight into prescribing and dispensing conduct. Rather than using this information to prevent diversion and fulfill their obligations under New Mexico law, Manufacturer Defendants were part of a plan, effected in lock step with other Defendants, to increase the sales of opioids above any legitimate purpose, which caused the DEA to inflate beyond any therapeutic, medical, scientific, or research need, the quota for these prescription drugs.

241. Defendants have a duty to, and are expected to, be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. Defendants breached their duties by failing to: (a)control the supply chain; (b)prevent diversion; (c)report suspicious orders; and (d)halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

ii. Defendants Understood the Importance of Their Reporting and Due Diligence Obligations

242. All Defendants were well aware that they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

243. Recently, Defendant Mallinckrodt admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[75] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b)… [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

244. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association to which the Big Three (and Manufacturer Defendants) belong, and the National Association of Chain Drug Stores ("NACDS"), where Walgreens sits on the Board of Directors, have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[76] Guidelines established by the HDA also explain that distributors, "[a]t the center of a

[75] https://www.justice.gov/usao-edmi/press-release/file/986026/download

[76] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

sophisticated supply chain… are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[77]

245. The DEA also repeatedly reminded the Defendants of their obligations under federal law, mirrored in and incorporated by New Mexico law, to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[78] The Big Three Distributor Defendants have each attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

246. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for

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[77] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

[78] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

lawful purposes. This responsibility is critical, as ...the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[79] The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[80] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[81]

247. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[82] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007),

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[79] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[80] *See id.*

[81] *See id.*

[82] *See* 2007 Rannazzisi Letter.

which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[83]

iii. Despite Repeated Admonitions, Defendants Have Repeatedly Violated their Obligations

248. Distributor Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

249. Governmental agencies and regulators have confirmed (and in some cases Distributor Defendants have admitted) that Distributor Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

250. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, McKesson, CVS, and Walgreens:

a. On April 24, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain
effective controls against diversion of hydrocodone;

c. On December 5, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

[83] *See* id.

d. On December 7, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California, and Denver, Colorado;

h. On September 30, 2009, the DEA issued an Order to Show Cause against the Walgreens retail facility in San Diego, California ("San Diego Facility").

i. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 Walgreens MOA") with DEA in relation to its San Diego Facility. The MOA provided that "Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations.

j. On February 2, 2012, DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

k. On February 2, 2012, DEA issued *Orders to Show Cause and Immediate Suspension Orders* against Holiday C.V.S. L.L.C. d/b/a CVS/Pharmacy #00219 as well as CVS/Pharmacy #05195 for continually dispensing controlled substances to customers under circumstances indicating that the drugs were diverted from legitimate channels, misused, or abused. On August 31, 2012, the Administrator of DEA ordered the full revocation of

both pharmacies' DEA registration for violations of the CSA and implementing regulations.

l. On September 14, 2012, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Walgreens' Distribution Center in Jupiter, Florida.

m. On June 11, 2013, Walgreens agreed to pay $80 million in civil penalties to resolve DEA's investigations. It also entered into another Memorandum of Agreement with DEA in which it acknowledged that its distribution and dispensing practices were not fully consistent with its obligations under the CSA.

251. Both Defendant Cardinal Health and Defendant McKesson have also been fined for violations involving pharmacies or distribution facilities in New Mexico. On December 23, 2016, Cardinal Health agreed to pay a $34 million fine to DEA to settle allegations raised in the February 2, 2012 *Order to Show Cause and Immediate Suspension Order* that it violated the CSA by failing to report suspicious orders sent from its Lakeland, Florida distribution centers to pharmacies in Florida.[84]

252. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders, including from its distribution facility in Landover, Maryland. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[85]

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[84] The Settlement also included a related $10 million settlement in New York. *Id.*; Margie Manning, *Cardinal Health Agrees to $44 M Settlement in Lakeland, New York Cases*, Tampa Bay Business Journal (December 23, 2016).

[85] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan.

253. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required."[86] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations . . . at the McKesson Distribution Centers" including the McKesson Distribution Center located in Landover, Maryland. These failures were direct violations of the 2008 McKesson MOA with the DEA. Upon information and belief, the McKesson facility located in Landover supplied opioids to the City.

254. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[87] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion

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17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

[86] *Id.*

[87] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[88]

255. Even the far lesser-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four states. This penalty, too, was far less severe than investigators had recommended; as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[89]

256. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[90] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[91] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[92] "Instead, DEA officials said, the company raised its own self-imposed limits, known as thresholds, on

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[88] *Id.*

[89] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[90] *Id.* (alteration in original).

[91] *Id.* (quoting a March 30, 2015 DEA memo).

[92] *Id.*

orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[93]

257. Further, in a *60 Minutes* interview from fall of 2017, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die. "[94] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[95]

258. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[96] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[97]

259. At a hearing before the House of Representatives' Committee on Transportation and Infrastructure, Subcommittee on Economic Development, Public Buildings, and Emergency Management on May 8, 2018, the chief executives of McKesson and Cardinal, among others,

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[93] *Id.*

[94] Bill Whitaker, Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

[95] *Id.*

[96] *Id.* --

[97] *Id.*

testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. However, in fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

260. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

261. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of only two pages. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—more than 9,500 pills *per day*.

262. Further, as referenced above, Walgreens has also been repeatedly penalized for its illegal prescription opioid practices. Upon information and belief, based upon the widespread

nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of Walgreens, including in New Mexico.

263. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

264. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[98]

265. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

266. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[99]

267. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders

[98] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

[99] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.[100]

268. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause and Immediate Suspension Order, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on the number of prescriptions filled at the pharmacy to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[101]

269. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

270. For example, in January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled

[100] *Id.*

[101] *Id.*

substances—despite the context of soaring overdose deaths. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[102]

271. Manufacturers had knowledge of diversion as well and have failed to comply with their obligations to report and decline suspicious orders, and stop detailing suspicious prescribers. Sales representatives learned that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

272. Moreover, Manufacturer Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic,

[102] *Id.*

Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[103]

273. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this [is] an organized drug ring[.]"[104] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[105] This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

274. Mallinckrodt also failed to report suspicious prescribing. A former Mallinckrodt sales representative reports that he regularly visited a doctor over the course of 5 years. The doctor has now been criminally indicted. During the visits, the representative saw the doctor's office overflowing with patients, some of whom waited for up to 8 hours to see the doctor, and heard them bragging about earning $70,000 from selling prescriptions written by the doctor. Despite having around 300 doctors on his call list, the former sales representative's supervisor at Mallinckrodt instructed the sales representative to spend half of his time with the doctor because of the sales potential due to the doctor's prescribing. The sales representative and his supervisor

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[103] Meier, *Pain Killer*.

[104] Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, LOS ANGELES TIMES (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/

[105] *Id.*

did not report the doctor because his prescribing was very high, and the company made a lot of money from his prescribing.

275. These examples demonstrate how Manufacturer Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. The goal of the marketing strategy was to increase these Defendants' profits by convincing more doctors to prescribe opioids in higher and higher doses for long term use. Thus, these Defendants did identify doctors who were their most prolific prescribers, but not to determine if their prescribing was suspicious and, if so, report them. Defendants identified these prescribers to market to them and ensure they continued to prescribe more and more of Defendants' opioids.

276. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturer Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[106]

277. But given the closeness with which these Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Indeed, a Purdue

[106] Meier, *Pain Killer*, at 179.

executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

H. Defendants Worked Together to Sustain Their Market and Boost Their Profits

278. The Big Three, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock."[107] Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

279. Distributor Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits. Of course, increased sales volumes have

[107] *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).

also resulted in the oversupply of opioids and concurrent increases in addiction, overdose, and criminal diversion across the United States and in and around the City.

280. Upon information and belief, each of the Distributor Defendants also worked together, and with Manufacturer Defendants, through trade or other organizations, such as the HDA, the National Association of Chain Drugstores, and the Pain Care Forum ("PCF"),[108] to safeguard the market for opioids and the distribution of opioids.[109]

281. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.[110] All of the Manufacturer Defendants were members as well.[111]

282. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Big Three with the opportunity to work closely with each other and with opioid manufacturers, confidentially, to develop and further their common purpose and interests.

283. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributors advertise these conferences as an opportunity to "bring together high-level executives, thought leaders and influential managers … to hold strategic business discussions on the most pressing industry issues."[112] The conferences also gave the Distributors and Manufacturer Defendants "unmatched opportunities to network

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[108] The Pain Care Forum is a lobbying organization.

[109] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

[110] https://www.healthcaredistribution.org/about/membership/distributor (H.D. Smith would have been represented by Smith Drug Company, Div. J M Smith Corporation.)

[111] https://www.healthcaredistribution.org/about/membership/manufacturer.

[112] *Business and Leadership Conference—Information for Manufacturers*, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed on Sept. 14, 2017).

with [their] peers and trading partners at all levels of the healthcare distribution industry."[113] The HDA and its conferences were significant opportunities for the Big Three to interact at a high level of leadership.

284. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[114]

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[113] *Id.*

[114] Councils and Committees, Healthcare Distribution Alliance, (accessed on December 11, 2017), available at https://www.healthcaredistribution.org/about/councils-and-committees

285. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, shipping notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers…" Upon information and belief, the Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

286. The Big Three also coordinated with each other and opioid manufacturers in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[115] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, as is described in this Complaint.

287. Distributor Defendants also worked together through HDA and National Association of Chain Drugstores ("NACDS"). The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These

[115] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

statements support the inference that Distributor Defendants worked together to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

288. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts to engage in the unlawful sale of prescription opioids.

289. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances ("Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

290. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Here, it is apparent that Defendants found the same

balance – an overwhelming pattern and practice of failing to identify, report, or halt suspicious orders, and failure to prevent diversion.

291. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturer and Distributor Defendants did this through their participation in the PCF, HDA, and the NACDS.

292. Upon information and belief, the Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

I. Defendants Ignored Red Flags of Abuse and Diversion

293. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in DEA's confidential ARCOS database.[116] ARCOS, which stands for Automation of Reports and Consolidated Orders System, tracks controlled substances distribution based on data provided by manufacturers and distributors. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants and Manufacturer Defendants, but has not been disclosed to the public.

294. Yet, publicly available information confirms that Defendants funneled far more opioids into and around the City than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information

[116] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting the City.

295. The City's information and belief rests upon the following facts:

(a) distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) The Big Three, Manufacturer Defendants, regularly visit pharmacies and/or doctors to promote and provide their products and services, which allows them to observe red flags of diversion. Similarly, Walgreens has direct access to the transaction data of its chain of retail pharmacies.

(c) The Big Three together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

(d) Walgreens has been relatedly penalized for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests they are the product of national policies and practices;

(e) Performance metrics and prescription quotas adopted by the national retail pharmacies such as Walgreens for its retail stores contributed to their failure. The result is both deeply troubling and entirely predictable: opioids flowed out of national retail pharmacies and into communities throughout the United States. The policies remained in place even as the epidemic raged.

296. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. Walgreens, for example, had direct access to the prescription rates of its retail pharmacies.

297. Distributors have a duty to know their customers and the communities they serve. Wholesale distributors, such as the Big Three, developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help distributors identify suspicious orders or customers who were likely to

divert prescription opioids.[117] The "know your customer" questionnaires informed distributors of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

298. According to testimony by a former Executive Chairman of the Board of Cardinal at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports, and, as explained above, Walgreens would have had this information from their own pharmacies.

J. Santa Fe County, the Area Within Which the City is Located, is a High Intensity Drug Trafficking Area Significantly Harmed by the Opioid Epidemic.

299. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around the City, should have investigated, terminated suspicious orders, and reported potential diversion to law enforcement.

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[117] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Administration, available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf; Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McGuireWoods LLC, available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf.

300. The City has been designated a High Intensity Drug Trafficking Area by the Office of National Drug Control Policy.[118] Due to the vast openness of the geography, as well as the proximity to Mexico, the region has been deemed "a major contributor to the flow of narcotics into and through" New Mexico.[119] The region continues to see increases in the amount of Mexican black tar heroin.[120]

301. Given the widespread abuse and misuse of opioids, it is unsurprising that some practitioners have begun to profit from this dangerous marketplace. Despite clear regulations under the New Mexico Administrative Code, some practitioners instead choose to violate their legal obligations and duties in order to profit from prescribing dangerous opioid controlled substances to patients.

302. Defendant Broderson pled guilty on September 19, 2016 to issuing patients multiple, often overlapping prescriptions for hydrocodone that significantly exceeded the medically recommended dosages.[121] Nurse Broderson also admitted to instructing patients to deliver the hydrocodone to her, and further admitted that the prescribing and retaining hydrocodone exceeded any legitimate medical purpose and was outside the usual course of professional practice. Nurse Broderson's conduct was further outside the usual course of professional practice as she had been operating as a solo practitioner providing psychiatric services, not pain management services.

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[118] *See* https://www.ncjrs.gov/ondcppubs/publications/enforce/hidta2001/nmex-fs.html

[119] *Id.*

[120] *Id.*

[121] *See* https://www.justice.gov/usao-nm/pr/nurse-practitioner-santa-fe-sentenced-probation-unlawful-possession-controlled-substances

303. In July 2018, Defendant Dr. Bray-Morris voluntarily surrendered his license to practice medicine in New Mexico.[122] Dr. Bray-Morris did so in light of the New Mexico Medical Board (the "Board") finding that he:

a. Violated a prior stipulated agreement to abstain from personal use of opioid controlled substances;

b. Forged signatures on mandatory urine drug screenings;

c. Prescribed large amounts of controlled substances to patients without medical justification, specifically including placing patients on a potentially deadly regimen of at least one opioid, one benzodiazepine, and carisoprodol, a muscle relaxer;

d. Providing patient care deviating from the standard of care;

e. Failing to screen patients for substance abuse disorders;

f. Diverting the controlled substances he prescribed to patients for his own personal use;

g. Falsifying medical records; and

h. Failing to obtain prescription monitoring reports as required by law when treating chronic pain.

304. Nurse Broderson and Dr. Bray-Morris contributed to the region-wide opioid epidemic, encouraged by Manufacturer Defendants' misleading statements and marketing, facilitated by Pharmacy Defendants' failure to uphold their duties to monitor for red flags of diversion, and assisted by Distributor Defendants' failure to implement a system to monitor and report suspicious orders.

305. In response to the epidemic, New Mexico, in conjunction with federal law enforcement, has set up the New Mexico Heroin and Opioid Prevention and Education ("HOPE") Initiative. Nurse Broderson was a target of the HOPE Initiative investigation, which

[122] *See* http://docfinder.docboard.org/nm_orders/Bray-Morris,%20John.pdf

led to her arrest. In 2016, the HOPE Initiative led to the arrest of a couple charged with major drug trafficking charges, including conspiracy to distribute oxycodone, oxymorphone, and alprazolam. The couple twice distributed large quantities of opioid controlled substances in the City, as well as six times in Bernalillo County, New Mexico. Ultimately, the couple pled guilty to the charges.[123]

306. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in and around the City.

K. Defendants Hid Their Lack of Cooperation With Law Enforcement and Falsely Claimed To Be Actively Working To Prevent Diversion

307. When a wholesaler or manufacturer does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action–or may not know to take action at all.

308. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement.

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[123] *See* https://www.justice.gov/usao-nm/pr/albuquerque-couple-plead-guilty-prescription-drug-trafficking-and-money-laundering

Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

309. More generally, the Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that, We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone."[124] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[125] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.[126] A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[127]

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[124] Cardinal website, Ethics and Governance, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html.

[125] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[126] Cardinal website, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/community-relations/population-health/rx-drug-misuse-and-abuse.html.

[127] Lenny Bernstein *et al., How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job'*, The Washington Post (Oct. 22, 2016), http://wapo.st/2vCRGLt.

310. Similarly, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion.[128] Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our United States."[129]

311. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances."[130] A company spokeswoman, Lauren Moyer, also provided assurance that, "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[131]

312. Walgreens also publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription. Citing these efforts, Walgreens promotes itself as committed to

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[128] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

[129] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[130] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[131] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

313. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[132]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

314. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

315. These public statements created the false and misleading impression that the Distributor Defendants rigorously carried out their duty to report suspicious orders, exercised due diligence to prevent diversion of these dangerous drugs, and worked on their own accord to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

316. Manufacturer Defendants also misrepresented their compliance with legal duties and cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it publicly and repeatedly touted its "constructive role in the

[132] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[133]

317. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

318. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create ... That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[134] Purdue's statement on "Opioids Corporate Responsibility" likewise states that, "For many years, Purdue has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government."[135] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[136]

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[133] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

[134] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ .

[135] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/news-media/opioids-corporate-responsibility/ .

[136] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-

319. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. Purdue aims to distance itself from past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

320. Mallinckrodt made misrepresentations regarding its efforts to fight opioid addiction. Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that, "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."[137] The truth, of course, is that Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders, which supplied far more opioids than were justified and led to diversion of opioids in and around the City and other cities, counties, and states.

321. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

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on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

[137] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

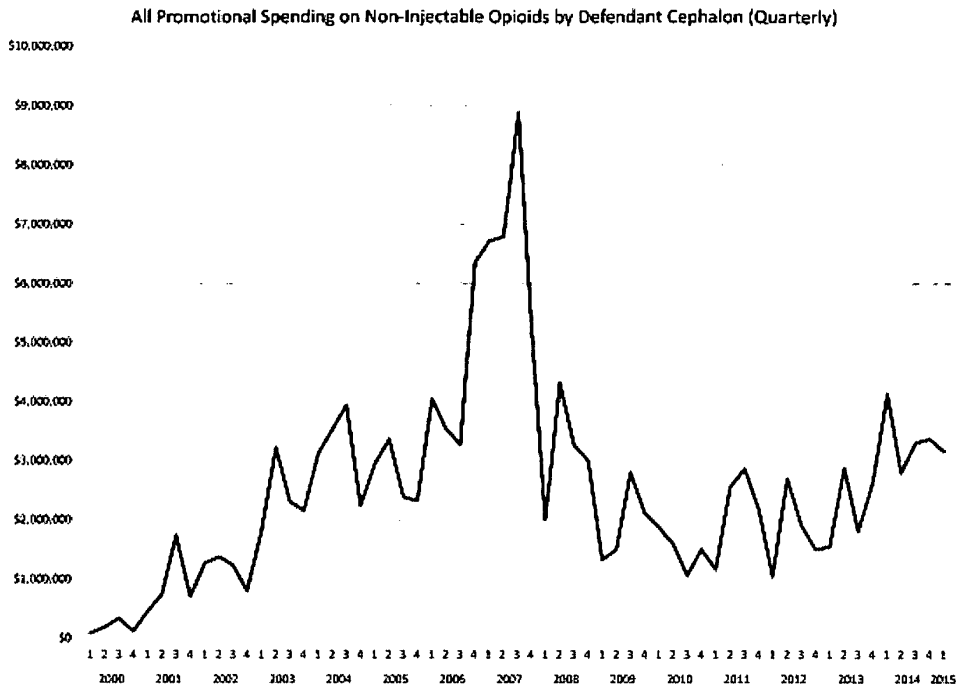
L. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed The City and Its Residents

322. Manufacturer Defendants' misrepresentations and deceptive conduct prompted health care providers in and around the City to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing Manufacturer Defendants overcame barriers to widespread prescribing of opioids for chronic pain. The Distributor Defendants recklessly distributed opioids and failed to meet their regulatory obligations in New Mexico.

323. Defendants' deceptive marketing and illegal distribution practices substantially contributed to an explosion in the use of opioids across the United States. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

324. Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

325. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:


All Promotional Spending on Non-Injectable Opioids by Defendant Cephalon (Quarterly)
$10,000,000
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$8,000,000
$7,000,000
$6,000,000
$5,000,000
$4,000,000
$3,000,000
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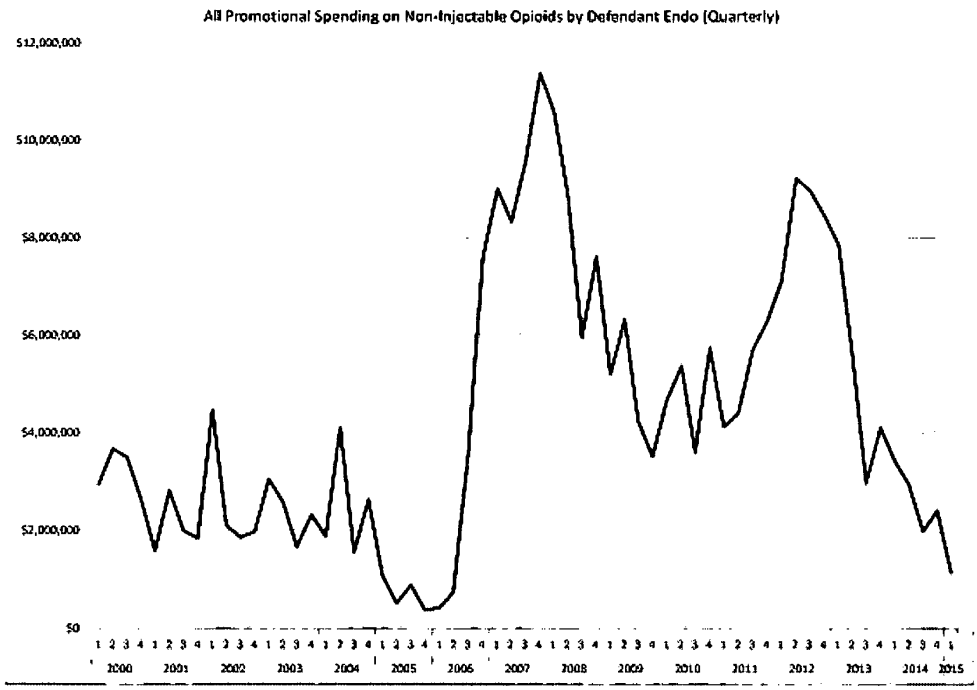
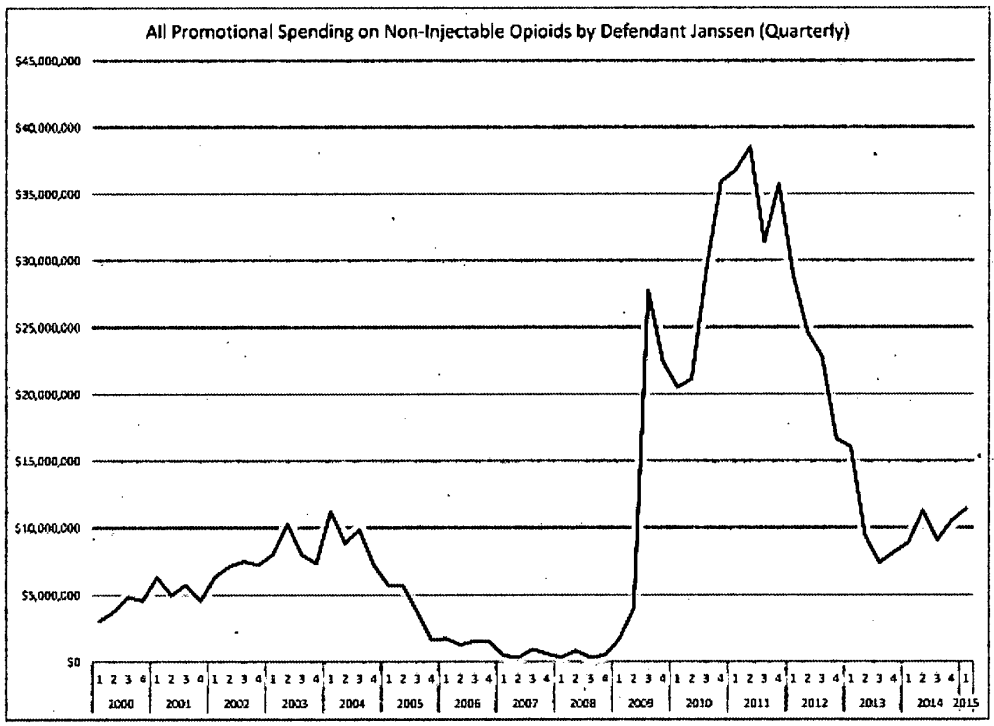
2015

326. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):

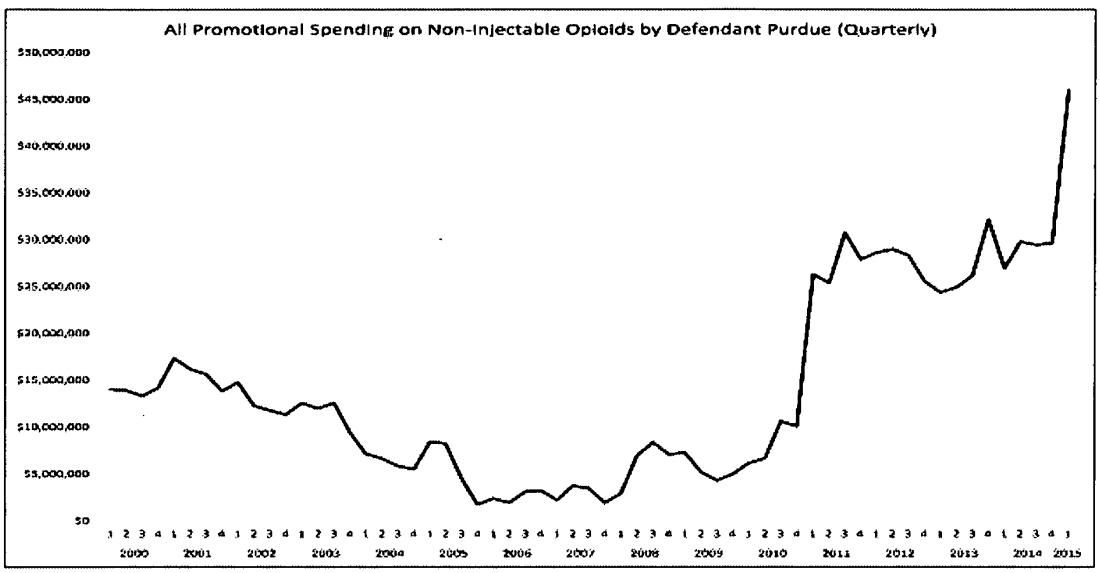


327. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



328.

Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a



total of $110 million that year), and continued to rise through at least 2015.

329. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in and around the City. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[138]

[138] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

330. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[139]

331. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturer Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

332. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the

[139] *See* Murthy, *supra*.

CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[140]

333. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[141]

334. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[142]The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[143]

M. The City Continues to Be Burdened with Significant Expenses as a Result of All Defendants' Malfeasance in Causing the Opioid Epidemic.

335. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

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[140] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths—United States, 2000–2014*, Am. J. of Transplantation 16.4 (2016): 1323-1327.

[141] Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[142] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[143] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).

336. The overprescribing of opioids causes an increase in additional medical conditions. A growing number of people need medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by the *Washington Post*, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effect medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves.

337. The deceptive marketing and overprescribing of opioids also has a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse.[144] Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin.[145] However, according to the CDC Guidelines, there has been a significant increase in the prescribing of opioids to adolescents and children for headaches and injuries.[146]

338. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid

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[144] U.S. Pharmacist, *Legitimate Opioid Use Prior to High School Graduation Increase Abuse Risk*, available at https://www.uspharmacist.com/article/legitimate-opioid-use-prior-to-high-school-graduation-increases-abuse-risk.

[145] National Institute of Health, *Prescription Opioid Use is a Risk Factor for Heroin Use,* available at https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use.

[146] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, *Morbidity and Mortality Weekly Report* 3 (March 18, 2016).

withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

339. Contrary to Defendants' misrepresentations, most of the illicit opioid use originates from prescribed opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

340. Those who are addicted to prescription opioid painkillers are 40 times more likely to become addicted to heroin. Prescription opioids, at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. Not surprisingly, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

341. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury. Fentanyl is a relatively recent, even more

deadly problem stemming from the prescription opioid epidemic. Fentanyl is a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into communities across the United States. The City's prosecutors have noticed an increase in criminal cases involving the combination of heroin and fentanyl.

342. The burdens imposed on the City are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Defendants' illegal actions.

N. Defendants Fraudulently Concealed Their Misconduct

343. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

344. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded

marketing, third party advocates, and professional associations. Purdue, Endo, Teva, Mallinckrodt, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, Mallinckrodt, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

345. Manufacturer Defendants successfully concealed from the medical community, patients, and the City, facts sufficient to arouse suspicion of the claims that the City now asserts. The City did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

346. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to publicly release the information they have provided to the DEA for the ARCOS database, which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

347. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and pharmacy orders.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

348. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

349. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of the public in and around the City by their production, promotion, marketing, distribution, and sale of opioids for use by residents of the City. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of thousands of the City's residents and interferes with the enjoyment of life in violation of New Mexico law. That the criminal public nuisance statute allows private citizens to abate a public nuisance under NMSA 30-8-8.

350. Prescription opioid abuse, addiction, morbidity, and mortality are a temporary public nuisance in the City, which remains unabated. The unlawful conduct by the Defendants has created these hazards to public health and safety, the public health epidemic, and the state of emergency described in this complaint.

351. The health and safety of the citizens of the City, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the City's citizens and residents. Defendants' acts and omissions offend, significantly and unreasonably interfere with, and cause damage to the public rights common to all, such as the public health, public safety, public peace, moral standards, and the public comfort. Defendants have control over their conduct in and around the City, and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance.

352. Defendants knew, or should have known, that their promotion and irresponsible distribution of opioids (in violation of their monitoring and reporting obligations) would create or assist in the creation of a public nuisance.

353. Defendants are liable for a public nuisance because they acted without lawful authority in knowingly creating and maintaining opioid use at such volumes and degree as to create an epidemic, which clearly affects a number of citizens, is injurious to public health, safety, morals and welfare, and interferes with the exercise and enjoyment of public rights.

354. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public and the abatement statute allows "public officers or private citizens" to bring an action to abate a public nuisance. *City of Albuquerque v. State ex rel. Village of Los Ranchos de Albuquerque*, 1991-NMCA-015, ¶ 17, 111 N.M. 608, 808 P.2d 58 ("A public nuisance is a wrong that arises by virtue of an unreasonable interference with a right common to the general public.") (citing Restatement (Second) of Torts § 821B(1); further cit. om.). The Defendants' conduct described herein significantly interferes with public health, safety, peace, comfort, and convenience. All Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Manufacturer Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe. Moreover, by failing to report or cease supplying known pill mills in and around the City, Defendants exacerbated the opioid crisis in the City, and failed to limit its reach.

355. In addition and independently, Defendants' conduct invades a legally protected interest. Defendants' conduct constitutes an unreasonable interference because *inter alia* each Distributor Defendant has violated New Mexico law. *E.g., inter alia,* NMSA 1978, §§ 30-31-1 to -41; 61-11-6; 16.19.8.13, 16.19.20.48 NMAC. The Distributor Defendants have permitted dangerous drugs under their control to be diverted for illicit purposes such as to injure the City and its residents.

356. The Manufacturer Defendants have violated New Mexico law. NMSA 1978, §§ 30-31-1 to -41; 30-16-6. These Defendants conducted a fraudulent campaign to misrepresent the safety and efficacy of opioid drugs and to ensure their widespread use for chronic pain knowing that Defendants were specifically misrepresenting the high risk of severely harmful addiction.

357. All Defendants knew or should have known that distributing or selling opioids in ways that facilitated and encouraged their flow into the illegal secondary market, distributing or selling opioids without maintaining effective controls against diversion, choosing not to stop or suspend shipments of suspicious orders, choosing not to report suspicious prescribing, distributing or selling opioids to pill mills when Defendants knew or should have known the opioids were being prescribed by pill mills, and filling prescriptions for opioids despite the existence of unresolvable red flags of diversion would create or assist in the creation of a public nuisance.

358. Because Defendants have maintained their opioid drug selling activities contrary to law, and because Defendants' conduct has unreasonably interfered with a right common to the general public, Defendants are liable for public nuisance per se. *See Espinosa v. Roswell Tower, Inc.,* 1996-NMCA-006, ¶ 10, 121 N.M. 306, 910 P.2d 940 ("An activity conducted or maintained contrary to law may be a public nuisance per se when the activity unreasonably interferes with a right common to the general public.").

359. Defendants' unreasonable interference with a right common to the public is of a continuing nature. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the City. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because inter alia these drugs are defined under New Mexico law as substances posing a high potential for abuse and severe addiction. NMSA 1978, §§ 30-31-5(B), 30-31-7(A). Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

360. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The harm is ongoing, producing long-lasting damage. Defendant's conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peach, health, order, and safety.

361. Defendants' conduct directly and proximately caused injury to the City and its residents. The City suffered special injuries distinguishable from those suffered by the general public. As discussed herein, the City has incurred substantial costs from investigating, monitoring, treating, policing, and attempting to remediate the opioid epidemic.

362. The City's fire department spent over $212,000 in the Fire-Years 2017-2018 on opioid overdose patients. From January 1 2011 to December 31 2018 the fire department documented naloxone administration in 1507 patient encounters and spent $23,755 on naloxone alone in the Fire Years 2014 – 2015 through Fire Years 2017 – 2018, These costs represent the direct cost for naloxone and do not include other/indirect costs of administering it, such as IV supplies, nasal administration devices and needles, among other equipment.

363. The community services department has expended $1,251,000 in Children Youth Commission and Human Services Committee funding since 2009 on non-profits in the City to provide opioid education, opiate use prevention services, and treatment for youth and adults, which expenditure has been necessitated by the actions of defendants.

364. The City's Police Department's LEAD Program "Law Enforcement Assisted Diversion Program," targeting the 100 eligible population who cause property crime offenses due to their opioid use, costs $4.2million.

365. The staggering rates of opioid and heroin use resulting from the Distributor Defendants' abdication of their gate-keeping duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids made opioids a recreational drug of choice among the City's teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those residents of the City who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs for the City's employees and the City's residents.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More pills sold by Defendants led to more addiction, with many addicts turning from prescription pills to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement in the City.

i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the City.

j. Defendants' interference with the comfortable enjoyment of life in the City is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

363. The City has sustained specific and special injuries because its damages include *inter alia* health services and law enforcement expenditures, as described in this Complaint. The public nuisance, i.e., the opioid epidemic, created, perpetuated, and maintained by all Defendants can be abated and further recurrence of such harm and inconvenience abated.

WHEREFORE, the City. seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement of the public nuisance, payment to the City of monies necessary to abate the public nuisance and any other monetary compensation to which the City may be entitled, compensatory and/or punitive damages and any other damages as allowed by law, attorney fees and costs, and pre- and post-judgment interest.

COUNT II
Racketeering Act
(Against Manufacturer Defendants)

364. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

365. The City has standing pursuant to NMSA 1978, § 30-42-6(A), because the City has sustained injury as outlined in this Complaint.

A. The Opioids Marketing Enterprise.

366. Defendants formed an association-in-fact enterprise (occ. "Opioids Marketing Enterprise"), and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in New Mexico. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; and (b) the Front Groups, including their employees and agents; and (c) the KOLs.

367. Defendants, the Front Groups, and the KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity.

368. Defendants conducted the Opioids Marketing Enterprise, and participated in the enterprise, by engaging in a pattern of racketeering activity.

369. Defendants received proceeds derived from a pattern of racketeering activity in which Defendants participated, and used or invested at 1east a part of the proceeds or the proceeds derived from the investment or use, in the acquisition of an interest in, or the establishment or operation of, the Opioids Marketing Enterprise.

370. Defendants engaged in a pattern of racketeering activity to acquire or maintain an interest in or control of the Opioids Marketing Enterprise.

371. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systemic links for a common purpose: to ensure the prescription of opioids for chronic pain.

372. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented - either affirmatively or through half-truths and omissions - to the general public, the City, and New Mexico consumers, the risks and benefits of using opioids for chronic pain. The Opioids Marketing Enterprise concealed from the public, the City, and New Mexico consumers, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

373. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

374. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids.

Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers and the City. But for the Opioid Marketing Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioids Marketing Enterprise's scheme and reaped substantial benefits.

375. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

376. The Front Groups and KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity including multiple instances of fraud, they knowingly made material misstatements or omissions to City and City area physicians, consumers, the City, and the general public in furtherance of the fraudulent scheme, including but not limited to the facts that:

a. it was rare, or there was a low risk, that Defendants' opioids could lead to addiction;[147]

b. the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;[148]

[147] APF, *Treatment Options* (sponsored by Cephalon and Purdue); APF, *Policymaker's Guide* (sponsored by Purdue).

c. opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult;[149]

d. doctors could increase opioid dosages indefinitely without added risk;[150]

e. long-term opioid use improved patients' function and quality of life;[151] and,

f. Purdue's OcyContin provided 12 hours of continuous pain relief.[152]

377. Defendants alone could not have accomplished the purpose of the Opioids Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than Defendants themselves. Without these misrepresentations, the Opioids Marketing Enterprise could not have achieved its common purpose.

378. The impacts of the Opioids Marketing Enterprise's schemes are still in place—i.e., the opioids continue to be prescribed and used for chronic pain throughout the City and surrounding communities, and the epidemic continues to consume the resources of the City's health care insurance, emergency response providers, community health providers, and law enforcement system.

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[148] *See, e.g.,* Mark S. Wallace, M.D., Dir., Ctr. for Pain Medicine, Univ. of Cal. San Diego, National Initiative on Pain Control, *Opioid Analgesic Slide Module* (sponsored by Endo).

[149] APF, *A Policymaker's Guide* (sponsored by Purdue).

[150] *Id.*; APF, *Treatment Options* (sponsored by Cephalon and Purdue); McCaffery & Pasero (editor is a key opinion leader for Endo).

[151] APF, *Treatment Options* (sponsored by Cephalon and Purdue); Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007); NIPC, *Persistent Pain and the Older Patient* (2007).

[152] Press Release, Purdue Pharma, L.P., New Hope for Millions of Americans Suffering from Persistent Pain (May 31, 1996) ("OxyContin Tablets are taken every 12 hours, providing smooth and sustained pain control all day and all night.").

379. The foregoing evidences that Defendants, the Front Groups and the KOLs were each willing participants in the Opioids Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

B. Conduct of the Opioids Marketing Enterprise.

380. From approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation and management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. Defendants selected, cultivated, promoted and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. Defendants developed and disseminated pro-opioid treatment guidelines;

h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

i. Defendants concealed their relationship to and control of Front Groups and KOLs from the City and the public at large; and

J. Defendants intended that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

381. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to Front Groups and payments to KOLs to ensure that their representations were consistent with Defendants' messaging nationwide and throughout the State of New Mexico and in the City. Front Groups were dependent on Defendants for their financial support, and KOLs were professionally dependent on Defendants for the development and promotion of their careers.

382. The Front Groups also participated in the conduct of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages;

b. The Front Groups distribute promotional and other materials claiming that opioids could be safely used for chronic pain, and the benefit of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

309. The KOLs also participated in the conduct of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages;

b. The KOLs distributed promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

383. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment for prescriptions of Defendants' opioids by New Mexico patients and the City. The Scheme was a continuing course of conduct, and many aspects of it continue through to the present.

C. Pattern of Racketeering Activity.

384. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering as defined in NMSA 1978, Section 30-42-3. Defendants' conduct as described above constitutes fraud chargeable or indictable under the laws of New Mexico and punishable by imprisonment for more than one year, which is defined as racketeering. NMSA 1978, § 30-42-3(A)(6).

385. "Fraud consists of the intentional misappropriation or taking of anything of value that belongs to another by means of fraudulent conduct, practices or representations." NMSA 1978, § 30-16-6. Here, Defendants intended to and did by means of fraudulent misrepresentations regarding the benefits of opioid prescriptions for treating chronic pain, succeed in misappropriating City funds, including, for example:

a. Costs of prescriptions;

b. Public employees' health insurance prescription coverage costs;

c. Retired public employees' group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, NMSA 1978, § 10-7C-8 (1990); and,

d. Other employees' health and benefit costs.

386. Defendants made the misrepresentations regarding the opioids' benefits with actual fraudulent intent to deceive prescribers in the City, New Mexico government payor programs *(inter alia* Medicaid), and the City's patients. Defendants' deception was massively successful.

387. Defendants' racketeering activities also included violations of the New Mexico Controlled Substances Act, Sections 30-31-20 to -22, and each act is chargeable or indictable under the laws of New Mexico and punishable by imprisonment for more than one year. *See* NMSA 1978, § 30-42-3(A)(13) (defining controlled substance trafficking as racketeering); § 30-42-3(A)(19) (defining controlled substance distribution as racketeering). The Manufacturer Defendants did not act in accordance with the New Mexico Controlled Substances Act because they did not act in accordance with registration requirements as provided in that Act. *See* **NMSA** 1978, §§ 30-3l-12(B), 30-3l-13(C), 30-3l-16(A); 30-3l-24(A)(2, 3), 30-3l-25(A)(4). Among other infractions, Defendants did not comply with 21 U.S.C. § 823 and its attendant regulations *(e.g.,* 21 C.F.R. § 1301.74), which are incorporated into New Mexico statutes or the New Mexico Pharmacy Board regulations. The Defendants failed to furnish notifications required under the Substances Control Act. NMSA 1978, § 30-3l-24(A)(3). Relatedly, the Defendants omitted required reports. NMSA 1978, § 30-3l-25(A)(4). Trafficking in controlled substances in violation of Section 30-31-20 is defined as "racketeering." § 30-42-3(A)(13). Distribution of controlled substances in violation of Sections 30-31-21 and 30-31-22 is defined as "racketeering." NMSA 1978, § 30-42-3(A)(l9).

388. The pattern of racketeering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

389. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

390. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants', the Front Groups' and the KOLs' books and records. Indeed, an essential part of the successful operation of the Opioids Marketing Enterprise alleged herein depended upon secrecy.

391. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the City. Defendants, the Front Groups and the KOLs calculated and intentionally crafted the opioids marketing scheme to increase and maintain their increased profits, without regard to the effect such behavior had on consumers in the City. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

392. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to consumers in the City, Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

393. It was foreseeable to Defendants that the Front Groups and the KOLs would distribute publications and otherwise misrepresent that the benefits of using opioids for chronic pain outweighed the risks of doing so.

394. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. Damages

395. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the City to be injured in its business and property because the

City paid for opioid prescriptions for chronic pain for which they would not otherwise have paid and have sustained other damages as described in this Complaint.

396. The City's injuries were proximately caused by Defendants' racketeering activities. But for the misstatements made by the Defendants, the Front Groups, and the KOLs and the scheme employed by the Opioids Marketing Enterprise, the City would not have paid for opioid prescriptions.

397. The City's injuries were directly caused by Defendants' racketeering activities. Although the misstatements made by the Front Groups and the KOLs in furtherance of the Opioids Marketing Enterprise were directed primarily to health care providers, those providers did not have to make payments for opioids prescribed for chronic pain. Therefore, New Mexico health care providers did not suffer the same injuries alleged in the Complaint.

398. The City was most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for compensatory damages, treble actual damages, injunctive relief, and any and all damages allowed by law to be paid by Defendants, attorney fees and costs, costs of investigation, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT III
Fraudulent Misrepresentation
(Against Manufacturer Defendants)

399. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

400. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to the City and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

401. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturer Defendants have engaged in misrepresentations and knowing omissions of material fact.

402. Specifically, misrepresentations or omissions include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Purdue's claims OxyContin provides a full 12 hours of pain relief;

j. Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

403. By engaging in the acts and practices alleged herein, Defendants omitted material facts that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h. Manufacturer Defendants failed to report suspicious prescribers;

404. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and not supported by or contrary to the scientific evidence.

405. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead City prescribers and consumers.

406. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

407. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

408. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

409. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, it would have undertaken efforts to avoid payments of related claims.

410. The Defendants' misrepresentations caused the City to fail to recognize that the problems at issue here arise from a man-made epidemic, or to understand the nature and gravity of the harms. The City relied on the Defendants to act as responsible corporate citizens, and Defendants' conduct as described herein prevented the City from taking action in attempting to address root causes and otherwise to ameliorate the public health crisis.

411. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

412. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all

damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT IV
Negligent Misrepresentation
(Against Manufacturer Defendants)

413. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

414. Manufacturer Defendants individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

415. Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs in and around the City.

416. Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain, while understating their very serious risks, including the risk of addiction.

417. These false statements included but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life; Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

h. Purdue's claims OxyContin provides a full 12 hours of pain relief;

i. Purdue's and Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

418. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

419. Healthcare providers and residents in and around the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

420. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, the City would have undertaken efforts to avoid payments of related claims.

421. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

422. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT V

Negligence and Negligence Per Se
(Against all Defendants)

423. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein. A negligence claim requires the existence of a duty from a defendant to a plaintiff, breach of that duty, which is typically based upon a standard of reasonable care, and the breach being a proximate cause and cause in fact of the plaintiff's damages. We apply a four-part test to determine whether a negligence per se instruction is appropriate in a given case.

> (1) [T]here must be a statute which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly, (2) the defendant must violate the statute, (3) the plaintiff must be in the class of persons sought to be protected by the statute, and (4) the harm or injury to the plaintiff must generally be of the type the legislature through the statute sought to prevent.

Heath v. La Mariana Apartments, 2008-NMSC-017, ¶ 7, 143 N.M. 657, 659, 180 P.3d 664, 666; *Herrera v. Quality Pontiac,* 2003-NMSC-018, ¶7. All elements exist here.

424. Manufacturer Defendants, and Distributor Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in and around the City.

425. Manufacturer Defendants, and Distributor Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

426. Manufacturer Defendants, and Distributor Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility vis-a-vis the City. Their duty cannot be delegated.

427. In addition, Manufacturing and Distributor Defendants each had a duty under New Mexico law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

428. The Pharmacy Defendants have additional duties under the law to refuse to fill any prescription for a controlled dangerous substance which they have reason to believe, or should have reason to believe, was not issued for a legitimate medical purpose in the usual course of the prescriber's practice. The Pharmacy Defendants had a persistent duty to identify red flags of diversion, and to refuse to fill all such prescriptions presenting red flags.

429. Dr. Bray-Morris and Nurse Broderson had unique duties under the law, as licensed health care professionals, not to prescribe outside the usual course of practice and for other than a legitimate medical purpose.

430. The New Mexico statutes and regulations at issue, including without limitation NMSA 1978, Section 26-1-18; and Sections 16.19.8.13 and 16.19.20.48 NMAC, are public safety laws. As such, these laws were intended to protect the public welfare and safety, and the City is the proper Plaintiff to enforce these laws. Defendants have duties under inter alia these laws to protect against diversion of prescription opioids for non-medical and non-scientific purposes and to guard against, prevent, and report suspicious orders of opioids.

431. Upon information and belief, each of these Defendants repeatedly breached its duties.

432. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

433. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City and its communities; increased expenses for the City for healthcare, emergency response, and public safety.

434. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of New Mexico law for Manufacturer Defendants, and Distributor Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and

pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

435. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively marketing highly addictive opioids for chronic pain by misrepresenting the risks and benefits of such use would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants Reasonably prudent manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

436. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

437. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of all Defendants. It does not seek damages which may have been suffered by individual citizens of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants.

438. These Defendants breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

439. The misconduct alleged in this case is ongoing and persistent.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VI
Gross Negligence and Punitive Damages
(Against all Defendants)

441. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

442. By engaging in the above-described unfair acts or practices, Defendants acted wantonly or oppressively or with such malice as implies a spirit of mischief or criminal indifference to civil obligations. Defendants' conduct also was willful, reckless, and/or fraudulent. *See Clay v. Ferrellgas, Inc.*, 1994-NMSC-080, ¶ 12, 118 N.M. 266, 881 P.2d 11 ("To be liable for punitive damages, a wrongdoer must have some culpable mental state, . . . and the wrongdoer's conduct must rise to a willful, wanton, malicious, reckless, oppressive, or fraudulent level, ...") (citations omitted).

443. All the Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, distributing, and dispensing highly dangerous opioid drugs in and around the City.

444. All the Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

445. All the Defendants are part of a limited class of registrants authorized to legally market, sell, distribute, and dispense controlled substances, which places them in a position of great trust and responsibility vis a vis Plaintiff. Their duty cannot be delegated.

446. In addition, Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants each had a duty under New Mexico law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, to not to fill suspicious orders unless and until due diligence had eliminated the suspicion, and to not fill prescriptions issued outside the usual course of medical practice and for other than a legitimate medical purpose.

447. Upon information and belief, each of these Defendants repeatedly and intentionally breached its duties.

448. All Defendants acted with wanton and reckless disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

449. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

450. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities.

451. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of New Mexico law for Manufacturer Defendants, and Distributor Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution

whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

452. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain by misrepresenting the risks and benefits of such use would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants. Reasonably prudent manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

453. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

454. Reasonably prudent pharmacies would know that filling a prescription presented with unresolvable red flags of diversion would lead directly to diversion of opioid controlled substances.

455. Reasonably prudent health care practitioners would know that dispensing prescriptions for dangerous and highly-abused opioid controlled substances would lead directly to abuse, misuse, diversion into illicit channels, addiction, and potentially death.

456. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) and punitive damages resulting from the gross negligence of all Defendants. The City does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by these Defendants' actions.

457. All Defendants' conduct as described in this complaint constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the City, and also implies a thoughtless disregard of the consequences without the exertion of any effort to avoid them. All Defendants have acted wantonly and willfully by inflicting injury intentionally or, alternatively, they have been utterly indifferent to the rights of others, including the City. They acted as if such rights did not exist.

458. All Defendants conduct as described in this Count demonstrates wanton and willful disregard for others, including the City, and justifies an award of punitive damages.

459. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

460. The misconduct alleged in this case is ongoing and persistent.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VII
Unjust Enrichment
(Against All Defendants)

461. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

462. To prevail on a claim for unjust enrichment under New Mexico law, a plaintiff must show that another has been knowingly benefitted at one's expense in a manner such that allowance of the other to retain the benefit would be unjust. *City of Rio Rancho v. Amrep Sw. Inc.*, 2011-NMSC-037, ¶ 54, 150 N.M. 428, 260 P.3d 414, 429 (citation omitted).

463. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the City.

464. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

465. The City has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

466. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

467. These expenditures have helped sustain Defendants' businesses.

468. The City has conferred a benefit upon Defendants by paying for the cost of the harms caused by Defendants' improper marketing and distribution practices.

469. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

470. The City has paid for the cost of the harms caused by Defendants' improper marketing and distribution practices, and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Manufacturer Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure

to exercise due diligence in preventing diversion, all Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification.

471. Defendants have unjustly retained benefits to the detriment of the City, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

472. Defendants' misconduct alleged in this case is ongoing and persistent.

473. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence.

474. The City has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

PRAYER FOR RELIEF

WHEREFORE, the City requests the following relief:

a. A finding that by the acts alleged herein, Defendants have created a public nuisance;

b. For an injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

c. For an order directing Defendants to abate and pay damages for the public nuisance;

d. For a finding that Defendants were negligent and grossly negligent;

e. For compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

f. For treble actual damages;

g. For punitive damages;

h. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

i. For costs, filing fees, pre and post judgment interest, and reasonable attorney's fees; and

j. For all other and further relief to which this Court finds it is entitled.

DATED: July 9, 2019

The City of Santa Fe, New Mexico

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STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

CITY OF SANTA FE

Plaintiff,

D-101-CV-2019-01809

v.

CEPHALON, INC.;
TEVA PHARMACEUTICAL INDUSTRIES LTD;
TEVA PHARMACEUTICALS USA, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS INC.;
ENDO PHARMACEUTICALS, INC.;
CARDINAL HEALTH INC.;
ABBOTT LABORATORIES;
KNOLL PHARMACEUTICAL COMPANY;
ALLERGAN PLC f/k/a ACTAVIS PLC.;
ALLERGAN FINANCE LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.;
ALLERGAN SALES LLC; ALLERGAN USA INC.;
WATSON LABORATORIES, INC.;
WATSON PHARMA, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC., f/k/a ACTAVIS, INC.;
MCKESSON CORPORATION;
MCKESSON MEDICAL SURGICAL INC.;
CARDINAL HEALTH, INC.;
CARDINAL HEALTH 110 LLC;
CARDINAL HEALTH 200 LLC;
CARDINAL HEALTH 414 LLC;
AMERISOURCE BERGEN DRUG CORPORATION;
MALLINCKRODT LLC;
MALLINCKRODT PLC;
MALLINCKRODT BRAND PHARMACEUTICALS;
COVIDIEN PLC;
SPECGX LLC;
MCKESSON CORPORATION;
ABBVIE, INC.;

KNOLL PHARMACEUTICAL COMPANY;
CVS HEALTH;
WALGREENS BOOTS ALLIANCE INC, a/k/a WALGREEN CO.;
WAL-MART STORES, INC.;
JOHN BRAY-MORRIS, M.D.;
and NICOLE RENEE BRODERSON, N.P.

Defendants.

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND DEMAND FOR JURY TRIAL

I. PRELIMINARY STATEMENT

1. Plaintiff, the City of Santa Fe, New Mexico (the "City"), like many other communities across the United States, is struggling with an opioid crisis. Unlike the crack cocaine and crystal methamphetamine epidemics that preceded it, this drug crisis began with a corporate business plan. It started with a decision by pharmaceutical manufacturers to promote opioids deceptively and illegally to significantly increase sales and generate billions of dollars in revenue for these pharmaceutical manufacturers: Endo Pharmaceuticals Inc.; Endo Health Solutions Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Janssen Pharmaceutica, Inc. N/K/A Janssen Pharmaceuticals, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Mallinckrodt PLC; Mallinckrodt Brand Pharmaceutical, Inc.; Mallinckrodt LLC; and SpecGx LLC (collectively the "Manufacturer Defendants"), all of whom, used misrepresentations regarding the risks and benefits of opioids to enable the widespread prescribing of opioids for common, chronic pain conditions like low back pain, arthritis, and headaches.[1]

2. In addition, the Manufacturer Defendants, along with McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Boots Alliance d/b/a

[1] Consistent with the commonly accepted medical usage, the term "chronic pain" as used herein refers to non-cancer pain lasting three months or longer.

Walgreen Co., Wal-Mart Stores, Inc., and CVS Health, (collectively, "Distributor Defendants") failed to maintain effective controls, and to investigate, report, and take steps to terminate suspicious orders (e.g., orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency).

3. Further, Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., and CVS Health held special obligations under the law as registered retail pharmacies (collectively the "Pharmacy Defendants"). On thousands of occasions, the Pharmacy Defendants ignored unresolvable red flags and filled prescriptions outside the usual course of practice and for other than a legitimate medical purpose, leading directly to the diversion of millions of pills of highly abused opioid controlled substances.

4. Defendant John Bray-Morris, M.D. ("Dr. Bray-Morris") is a doctor operating a medical practice in the City. Dr. Bray-Morris recently agreed to voluntarily surrender his license to practice medicine in the State of New Mexico based upon his prescribing of dangerous opioid controlled substances in violation of New Mexico law. Defendant Nicole Renee Broderson, N.P. ("Nurse Broderson") is a nurse practitioner working in the City. She was convicted in 2017 of unlawfully dispensing dangerous controlled opioid substances. As a direct consequence of the actions of practitioners, including Dr. Bray-Morris and Nurse Broderson, the rampant use, overuse, and abuse of opioids has overwhelmed much of New Mexico, including the City and its residents.

5. The City brings this action to redress Defendants' campaign of unfairly, deceptively, and fraudulently marketing, promoting, and distributing opioids.

6. Manufacturer Defendants manufacture, market, and sell prescription opioid pain medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora,

Opana/Opana ER, Percodan, Percocet, Zydone, Xartemis XR, Exalgo, Nucynta/Nucynta ER, and Duragesic, and generic drugs such as oxycodone.

7. Distributor Defendants McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., Walgreens Boots Alliance d/b/a Walgreen Co., Wal-Mart Stores, Inc., and CVS Health distribute opioid medications, including the medications listed above, to pharmacies, pain clinics and other dispensaries across the United States and in and around the City.

8. Pharmacy Defendants review prescriptions issued from licensed and DEA-registered practitioners, such as physicians, and ultimately choose whether or not to fill the issued prescription for the end-user customer. Pharmacy Defendants are the final line of defense in preventing the diversion of opioid medications, such as those listed above, for improper use, abuse, or illicit sale.

9. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. Opioids can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience severe and often prolonged withdrawal symptoms. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e., to relief of pain) — requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

10. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain — where brief use limited the need for escalating doses and the risk of addiction — or for palliative (end-of-life) care. Consequently, the market for prescription opioids was sharply constrained.

11. As pharmaceutical manufacturers developed opioid products in the mid-1990s, they knew that to expand their market and profits, they needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Teva, Janssen, Endo, and Mallinckrodt began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, these Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use. From the day they made the opioids to the day the medicines were consumed in our communities, including in and around the City, the Manufacturer Defendants had control over the information that they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing more and more of their products by arguing, among other things, that they fail to meet the standard of care if their patients continue to complain of pain, the Manufacturer Defendants created a population of addicted patients, including in the City, who sought opioids at never-before-seen rates.

12. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, pharmacies, and individual defendants (together, "Defendants"), who failed to maintain effective controls over the distribution of prescription opioids and against diversion, and who instead have actively sought to evade such controls and ignore red flags of potential diversion. Defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report or

take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

13. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggle with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin. From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids. Overdose deaths involving prescription opioids were five times higher in 2017 than in 1999.

14. As a direct and foreseeable result of Defendants' conduct, cities and counties across the United States, including the City, are now swept up in what the Centers for Disease Control ("CDC") has called a "public health epidemic" and what the U.S. Surgeon General has deemed an "urgent health crisis."[2] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescriptions opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who can no longer legally acquire or simply cannot afford prescription opioids.

15. This explosion in opioid use and the concurrent explosion in Defendants' profits have come at the expense of patients and have caused ongoing harm and damages to the City. As the then CDC director concluded in 2016: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.[3]

16. A substantial amount of the costs associated with opioid use and opioid abuse disorder is borne by government entities. The necessary and costly responses to the opioid crisis

[2] CDC, Examining the Growing Problems of Prescription Drug and Heroin Abuse (Apr. 29, 2014), available at http://www,cdc,give.washington/testimony/2014/t20140429.htm; Vivek H. Murthy, Letter from the Surgeon General, August 2016, available at http://turnthetiderx.org.

[3] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing thousands of children in foster care, among others.

17. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis. Within the next hour, five Americans will die from opioid overdoses; two babies will be born addicted to opioids and begin to go through withdrawal; and drug manufacturers and distributors will earn millions from the sale of opioids.

18. Accordingly, the City brings this action to hold Defendants accountable for their conduct and to seek damages, abatement, and any other injunctive and equitable relief within this Court's powers to redress and halt Defendants' unfair, deceptive, and unlawful practices.

II. PARTIES

A. Plaintiff

19. The City is an incorporated municipality in New Mexico with powers conferred upon it by, *inter alia*, Article 18 of the Municipal Code. Pursuant to N.M. Stat. Ann. § 3-18-1, the City has the capacity to sue.

20. The City is located in Santa Fe County, New Mexico, and has a population of 83,776. The City provides many services for its residents, including public health, public assistance, law enforcement, emergency care, and services for families and children. For its employees, the City also funds its own health insurance and workers' compensation programs.

21. The City brings this action on its own behalf and in the public interest.

B. Defendants

i. Manufacturer Defendants

22. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States, including in and around the City. Teva USA also sells generic opioids throughout the United States and in and around the City. In August 2016, Teva Pharmaceutical Industries Ltd., which is based in Israel and is Teva USA's parent company, acquired Allergan PLC, including the generic opioid business that Allergan had previously operated. These parties are collectively referred to herein as "Teva."

23. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, throughout the United States and in the City. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pleaded guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, Gabitril and Provigil, and agreed to pay $425 million.

24. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals,

Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit.

25. J&J imposes a code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. One code of conduct on Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

26. Similarly, the "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "pharmaceutical Companies of Johnson and Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, and sales associates must certify that they have "read, understood and will abide by" the code. Thus, the code governs all forms of marketing at issue in this case.

27. J&J also asserts control over Janssen through its management team. According to Janssen's website, the "leadership team that guides Janssen" contains several J&J executives.[4]

28. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. In addition, J&J made payments to Front Groups, discussed herein, who perpetuated and disseminated Defendants' misleading marketing messages regarding the risks and benefits of opioids.[5] Janssen and J&J are collectively referred to herein as "Janssen."

29. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and in and around the City, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

30. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

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[4] Members of Janssen's "leadership team" include Joaquin Duato, Vice Chairman of the Executive Committee, Johnson & Johnson; Paul Stoffels, M.D. Vice Chairman of the Executive Committee, Chief Scientific Officer, Johnson & Johnson; Jennifer Taubert, Executive Vice President, Worldwide Chairman, Pharmaceuticals, Johnson & Johnson; and, Scott White, Company Group Chairman, North American Pharmaceuticals, Johnson & Johnson. *See* https://www.janssen.com/about/our-leadership (last visited on April 24, 2019).

[5] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office, Staff Report, Fueling an Epidemic, Report Two, Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups, n. 23 ("Payments from Janssen include payments from Johnson & Johnson, Health Care Systems, Inc.").

31. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and in and around the City. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and in and around the City, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as an abuse-deterrent.

32. Mallinckrodt, PLC, is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, PLC. Prior to June 28, 2013 Mallinckrodt, LLC, was a wholly-owned subsidiary of Covidien PLC. Mallinckrodt Brand Pharmaceuticals is a Delaware Corporation which is wholly owned by Mallinckrodt PLC. Defendant SpecGx, LLC, is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt PLC. SpecGX currently manufactures and sells certain opioids which were previously manufactured by Mallinckrodt, LLC. Mallinckrodt, PLC, Mallinckrodt, LLC, Mallinckrodt Brand Pharmaceuticals, and SpecGx, LLC, are referred to as "Mallinckrodt."

33. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and

Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc. acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

34. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. In 2015, Mallinckrodt estimated, based on IMS Health data, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.[6] In 2017, Mallinckrodt paid a $35 million fine to the Department of Justice for its failure to report suspicious orders of its opioids.[7]

35. Collectively, Teva, Janssen, Endo, and Mallinckrodt are referred to herein as "Manufacturer Defendants."

iii. Distributor Defendants

36. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the United States, including in the City. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Based on Defendant Cardinal's own estimates,

[6] https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm.

[7] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

37. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including in and around the City. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

38. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including in the City. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware.

39. Cardinal, McKesson and AmerisourceBergen are, at times, collectively referred to herein as "The Big Three."

40. Walgreens Boots Alliance d/b/a Walgreen Co. ("Walgreens") includes a captive distributor that supplies pharmaceutical drugs and opioids to Walgreens pharmacies in New Mexico and throughout the United States, including in the City. Walgreens is headquartered in Deerfield, Illinois, and has distribution centers across the United States which distribute medications, including opioids, to various states, including New Mexico. Walgreens is registered to do business in New Mexico under the name Walgreen Co. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States and in the City. According to its website, Walgreens operates 9,560 retail stores with pharmacies, including 23 retail locations in the state of New Mexico, four of which operate within the City.

41. Wal-Mart Stores, Inc. ("Wal-Mart") is a Delaware corporation with its principal place of business in Arkansas. At all relevant times, Wal-Mart has sold and continues to sell prescription opioids at locations in and in close proximity to the City. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States and in the City. According to its website, Wal-Mart operates 3,646 retail stores with pharmacies, including 121 retail locations in the state of New Mexico, three of which operate within the City.

42. CVS Health ("CVS") is a Delaware corporation with its principal place of business in Rhode Island. During all relevant times, CVS Health has sold and continues to sell prescription opioids in and in close proximity to the City. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States and in and around the City.

43. Cardinal, McKesson, AmerisourceBergen, Walgreens, Wal-Mart, and CVS are at times collectively referred to herein as "Distributor Defendants."

44. The Distributor Defendants dominate the wholesale distribution market, including in the City. In order to increase their revenue, increase their profits, and grow their share of the prescription painkiller market, each of the Distributor Defendants distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling their fundamental duty under New Mexico statutes and New Mexico common law, to detect, report, and refuse to ship suspicious orders of opioids in order to prevent diversion of these dangerous drugs for non-medical purposes. Each has been cited and fined by the DEA and/or DOJ for failing to maintain effective controls against diversion. This unlawful conduct by the Distributor Defendants is a substantial cause for the volume of prescription opioids plaguing the City.

iv. Pharmacy Defendants

45. Additionally, Walgreens, Wal-Mart, and CVS are registered retail pharmacies in the state of New Mexico and are at times collectively referred to herein as "Pharmacy Defendants."

46. The Pharmacy Defendants represent 46.6 %, or nearly half of all prescription drug sales in the United States. In order to avail themselves of rebate programs with pharmaceutical distributors, and thus maximize their profits, the Pharmacy Defendants incentivized employees with volume-based bonuses for filling prescriptions for opioid controlled substances. In lieu of upholding their obligations under the law, Pharmacy Defendants instead consistently chose to ignore unresolvable red flags of diversion, and thus filled prescriptions without ensuring the prescription had been issued for a legitimate medical purpose in the course of usual medical practice.

47. Dr. Bray-Morris operated his medical practice out of the City. Dr. Bray-Morris prescribed opioid controlled substances to patients in and around the City for illegitimate and illicit purposes, include the abuse and diversion of those opioid controlled substances, in derogation of his duties under New Mexico law and under the New Mexico Medical Board.

48. Nurse Broderson was employed as a nurse practitioner working in the City, New Mexico. Nurse Broderson prescribed opioid controlled substances to patients in and around the City for illegitimate and illicit purposes, include the abuse and diversion of those opioid controlled substances, in derogation of her duties under New Mexico law and under the New Mexico Board of Nursing.

III. JURISDICTION AND VENUE

49. The venue for this claim is proper in the First Judicial District Court for Santa Fe County.

50. Venue as to each Defendant is proper in this Court because each of the Defendants carry on regular business in the City and/or the causes of action alleged in this Complaint arose in the City.

51. This Court has subject matter jurisdiction over this action.

52. This Court has personal jurisdiction over Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants pursuant to NMSA 1978, Section 38-1-16 because they transact business in the state of New Mexico, and have committed a tortious act within this State. The Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants have systematic and continuous contacts with the State of New Mexico.

53. This Court has personal jurisdiction over Defendant Dr. Bray-Morris because he is a resident of the City and operates his medical practice within the City.

54. This Court has personal jurisdiction over Defendant Nurse Broderson because she is a resident of the City and operates her medical practice within the City.

55. The City does not allege any federal cause of action, and to the extent that any pleading allegedly can be interpreted as stating any claim arising under federal law, any and all such federal claims are expressly disavowed. No federal question, substantial or otherwise, arises from the City's pleadings or is stated in said pleadings. Every claim and pleading by the City in this case can be adjudicated without resolving any federal question; therefore, federal questions are not raised and are certainly not necessarily resolved. Moreover, even assuming there is a federal question, which is denied, no such federal question is substantial to the federal system as a whole. *See Gunn v. Minton*, 568 U.S. 251 (2013). To the extent federal enforcement actions are discussed in this complaint, these pleadings do not state any federal claim or raise any federal question but rather are factual allegations showing Defendants' *mens rea* and the course of

Defendants' malfeasance as a factual matter. No federal question is substantial, is raised, or is necessarily adjudicated here because New Mexico statutory and regulatory requirements mirror federal duties with regard to controlled substances, and the City is exclusively relying on the state statutes, the state regulations, and state common law rather than on any federal law, regulation, or standard. The City makes no claim, and expressly disavows any alleged claim, against or directed to the United States or any agency thereof or any officer (or any person acting under that officer) of the United States or any agency thereof, in an official or individual capacity, for or relating to any act under color of such office; including without limitation, the City denies seeking, and expressly disavows, any recovery arising from McKesson Corporation's federal contract to supply prescription medication. *See* 28 U.S.C. § 1442. The statements in this paragraph are controlling notwithstanding anything alleged to the contrary.

IV. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

56. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. For the last two decades, Manufacturer Defendants have sought to successfully turn that consensus on its head, primarily by covering up the risk of addiction and overstating the benefits of using opioids long-term.

57. Through marketing that was as pervasive as it was deceptive, Manufacturer Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven, undermining general warnings in labels and elsewhere. These themes were repeated by sales representatives from other Manufacturer Defendants.

58. The Manufacturer Defendants blanketed the medical community with their misleading and deceptive misinformation campaign to change the narrative regarding the appropriate use of opioid medications and increase their profits. They enlisted trusted doctors, professional associations, and patient groups to disseminate their misrepresentations overstating the benefits of opioid use for chronic pain conditions and downplaying the risks of such use. As discussed more fully below, these doctors and groups appeared to be independent, but were funded and controlled by the Manufacturer Defendants to distort the public's and medical communities' perception of the risks, benefits, efficacy, and superiority of opioids to treat chronic pain. Misleading and deceptive messages were disseminated through seminars, physician Continuing Medical Education programs, speaker programs, websites, patient guides, and "scientific" and other publications given to doctors and stacked in patient waiting rooms.

59. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturer Defendants not only deceptively marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate Defendants' misleading marketing claims.

60. Manufacturer Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

A. Manufacturer Defendants Falsely Trivialized, Mischaracterized, And Failed To Disclose The Known, Serious Risk Of Addiction

61. Manufacturer Defendants, rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. These visits frequently coincide with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education." Upon information and belief, all of the Manufacturer Defendants had sales representatives who visited prescribers in the City.

62. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report that noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[8] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

63. To ensure that sales representatives delivered the desired messages to prescribers, Manufacturer Defendants directed and monitored their respective sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' "call notes" from each of their visits. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies and forbade them to use promotional materials not approved by the companies' marketing and compliance departments. They further ensured marketing consistency nationwide through

[8] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

national and regional sales representative training. Thus, upon information and belief,[9] their sales forces in New Mexico and the City carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the United States.

64. Manufacturer Defendants were aware of the strength of in-person marketing. The effects of sales calls on prescribers' behavior are well-documented in the literature. A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[10] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization.[11] An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.[12]

65. Manufacturer Defendants also used "key opinion leaders" ("KOLs") — experts in the field who were especially influential because of their reputations and seeming objectivity — to deliver paid talks and continuing medical education programs ("CMEs") that provided

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[9] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Santa Fe in the same manner as elsewhere.

[10] Ian Larkin *et al., Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. AM. MED. ASS'N 1785 (2017).

[11] Berdent ER, *et al., Information, Marketing and Pricing in the US Antiulcer Drug Market*, 85 AMER. ECON. REV. 101 (1995).

[12] Wazana A., *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?, 283* JAMA 378 (2000).

information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Manufacturer Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the Defendants' messages regarding the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."[13]

66. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Manufacturer Defendants exerted influence over these groups by providing major funding directly to them, as well. These "Front Groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain by overstating their benefits, and understating their risks. In many instances, Manufacturer Defendants distributed these publications to prescribers or posted them on their websites.

67. The FDA does not regulate all of the conduct in which the Manufacturer Defendants engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Manufacturer Defendants marketed their drugs. The

[13] Catan, Thomas, and Perez Evan, "A Pain-Drug Champion Has Second Thoughts," The Wall Street Journal, December 17, 2017, available at https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate the marketing messages or scripts relied on by Manufacturer Defendants' sales representatives or marketing funneled through third-parties. Upon information and belief, all of the messages described below were disseminated to prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, and other sources, including in and around the City.

i. Minimizing or mischaracterizing the risk of addiction

68. To convince prescribers and patients that opioids should be widely prescribed for long term use of chronic pain conditions and increase the market for and sales of opioids, Manufacturer Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted; (2) patients at greatest risk of addiction could be identified, (3) all other patients could safely be prescribed opioids, and (4) even high-risk patients could be prescribed opioids if closely managed.

69. Upon information and belief, sales representatives regularly omitted from their sales conversations with prescribers in and around the City any discussion of the risk of addiction from long-term use of opioids. These omissions rendered other arguably truthful statements about opioids false and misleading, and they both reinforced and failed to correct their prior misrepresentations regarding the risk of addiction.

70. Manufacturer Defendants also deceptively undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to specific, high-risk patients. According to these Defendants, doctors can screen patients to identify those who are likely to become addicted, and therefore could safely prescribe to everyone else. Manufacturer

Defendants discounted general concerns or warnings regarding addiction by reassuring doctors that their patients would not become addicted. These assurances were false and unsafe, as prescribers cannot accurately predict which patients are at higher risk of addiction.

71. In addition, upon information and belief, Manufacturer Defendants' sales representatives also failed to disclose to prescribers in and around the City the difficulty of withdrawing from opioids. Discontinuing or delaying opioids can cause intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This difficulty in terminating use is a material risk, which can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

72. Manufacturer Defendants falsely portrayed "true" addiction in its narrowest form.

73. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

74. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

75. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

76. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

77. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."[14]

78. Among its content, the website contained a handout titled *Oxycodone Safety for Patients*, which advised doctors that "[p]atients' fears of opioid addiction should be expelled."[15] The handout stated the following misleading information regarding the risk of addiction:

Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.

This handout is still available to prescribers and patients today.

79. In 2010, according to a Mallinckrodt Policy Statement, Mallinckrodt launched the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt further states: "Through the C.A.R.E.S. Alliance website, prescribers and

[14] https://web.archive.org/web/20070701065905/http://www.pain-topics.org:80/contacts_aboutus/index.php.

[15] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take." By 2012, the C.A.R.E.S. Alliance and Mallinckrodt were promoting a book titled *Defeat Chronic Pain Now!* The false claims and misrepresentations in this book include the following statements:

> a. "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
>
> b. "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
>
> c. "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
>
> d. "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."
>
> e. "[I]n our experience, the issue of tolerance is overblown."
>
> f. "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
>
> g. "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
>
> h. "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
>
> i. "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

This book is still available online.

80. Manufacturer Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as

many as 30-40%, of long-term users of opioids experience problems with addiction. In March 2016, the FDA emphasized the "known serious risk [] of ... addiction" — "even at recommended doses" — of all opioids.[16] That same month, after a "systematic review of the best available evidence" by a panel excluding experts with conflicts of interest, the CDC published the CDC Guideline for prescribing opioids for chronic pain. The CDC Guideline noted that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder" (a diagnostic term for addiction).[17] The CDC also emphasized that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[18] An additional study showed that nearly 60% of patients who used opioids for 90 days continued to use opioids five years later.

81. Furthermore, to the extent Defendants' labels mentioned the risks of addiction or abuse, Defendants' misleading and deceptive marketing minimized and trivialized these risks, reassuring physicians that they could prescribe opioids for long-term use because their patients were unlikely to become addicted.

ii. Manufacturer Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids

82. Manufacturer Defendants deceptively advised doctors to ignore signs of addiction as the product of an unfounded condition it called pseudoaddiction. Pseudoaddiction was a concept invented by Manufacturer Defendants to foster the misconception that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids

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[16] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sep. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[17] CDC Guideline at 2.

[18] *Id.* at 21.

or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel. By disseminating misleading information regarding pseudoaddiction, Defendants acted with the sole purpose of increasing their profits at the expense of patients.

83. The Federation of State Medical Boards ("FSMB"), a national organization representing state medical boards, including the New Mexico Medical Board, finances opioid- and pain-specific programs through grants from Manufacturer Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of "pseudoaddiction."

84. The Manufacturer Defendants sponsored the publication of *Responsible Opioid Prescribing*. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in and around the City.

85. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

86. Endo sponsored a National Initiative on Pain Control ("NIPC") CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of

untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

87. Manufacturer Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturer Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

88. The FAQs section of pain-topics.org, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'" [19]

89. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[20] and that physicians should "reassess [] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[21]

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[19] https://web.archive.org/web/20071026152321/http://pain-topics.org/faqs/index1.php#tolerance.

[20] CDC Guideline at 13.

[21] *Id.* at 25.

iii. Overstating the efficacy of screening tools

90. Manufacturer Defendants falsely instructed prescribers and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies will mitigate addiction risk. By using screening tools, these Defendants advised that doctors could identify those who are likely to become addicted and could safely prescribe to everyone else. Thus, Manufacturer Defendants undermined general concerns or warnings regarding addiction in drug labels and elsewhere by reassuring doctors that, despite the general warnings about addiction, their patients would not become addicted.

91. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients, and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations reassured doctors that opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients.

92. Upon information and belief, these Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors in and around the City.

93. Manufacturer Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which likely were attended by and were available to prescribers in and around the City.

94. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled

Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

95. A 2011 non-credit educational program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

96. Manufacturer Defendants' efforts to convince doctors that they could confidently prescribe to pain patients who did not intend to become addicted or abuse drugs were misleading. As these Defendants knew or should have known, sales to patients who doctor-shop (or visit multiple doctors to hide illicit use or overuse) constitute approximately only 1% of opioid volume.

97. Further, the 2016 CDC Guideline confirms the falsity of Manufacturer Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies — such as screening tools or patient contracts — "for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show *insufficient accuracy* for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[22]

[22] CDC Guideline at 28 (emphasis added).

B. Manufacturer Defendants Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-Term Use in Order to Increase their Profits

i. Mischaracterizing the benefits and evidence for long-term use

98. To convince prescribers and patients that opioids should be used to treat chronic pain to increase the number of opioid prescriptions and their profits, Manufacturer Defendants had to persuade the medical community of a significant upside to long-term opioid use. Assessing existing evidence, the 2016 CDC Guideline found that there is "*insufficient evidence* to determine the long-term benefits of opioid therapy for chronic pain."[23] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[24] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[25] The FDA also determined that opioid use disorder risk and overdose risk are present when opioids are taken as prescribed. As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

99. Upon information and belief, Manufacturer Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

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[23] *Id.* at 10.

[24] *Id.* at 9.

[25] Letter from Janet Woodcock, M.D., Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

100. Two prominent professional medical membership organizations, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Manufacturer Defendants. Upon information and belief, Manufacturer Defendants exercised considerable influence over the organizations' work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011. The statement was taken down from AAPM's website only after a doctor complained.

101. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturer Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain, but who frequently treat patients who suffer from chronic pain, such as the elderly. Eight of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Teva, nine from Janssen, and ten from Endo.

102. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug

companies, including Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

103. Dr. Gilbert Fanciullo, a retired professor at Dartmouth College's Geisel School of Medicine who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

104. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

105. Manufacturer Defendants also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions, and pose little risk to patients. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, IR oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results... should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[26] Yet, the authors conclude that "[t]his clinical experience shows that opioids

[26] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release*

were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[27] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

106. Teva deceptively marketed its opioids, Actiq and Fentora, for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

107. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

108. Despite this, Teva conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing[28] by its sales representatives to give doctors

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Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial, 266:4 Journal of Rheumatology 862-869 (1999).

[27] *Id.*

[28] Pharmaceutical detailing is a one-on-one marketing technique utilized by

the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

109. For example, Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

110. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

111. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain. The FDA does not regulate or approve journal publications sponsored by drug manufacturers, such as the Special Report.

112. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

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pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

113. In December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy ("REMS") for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl ("TIRF"). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not totally comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

ii. Overstating opioids' effect on patients' function and quality of life

114. Upon information and belief, Manufacturer Defendants also claimed to doctors in and around the City — without evidence — that long-term opioid use would help patients resume their lives and jobs.

115. Manufacturer Defendants' and Defendant-sponsored materials that, upon information and belief, were distributed or made available in the City, reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving daily function and quality of life for chronic pain patients." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively.

116. Similarly, since at least May 21, 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients

with physically demanding jobs, like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

117. Defendant Mallinckrodt's website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[29] Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009)—which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. Responsible Opioid Prescribing (2007), sponsored and distributed by Teva and Endo, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

c. Teva sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

d. Endo's NIPC website, painknowledge.com, claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

[29] Mallinckrodt Pharmaceuticals, Responsible Use, www.mallinckrodt.com/corporate-responsibility/responsible-use.

118. Likewise, Manufacturer Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

119. One pain specialist observed, "Opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[30] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.[31] Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.[32]

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[30] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[31] *Id.*

[32] Jeffrey A. White, et al., The Effect of Opioid Use on Workers' Compensation Claim

120. The CDC Guideline notes that "there is no good evidence that opioids improve pain or function with long-term use."[33] The FDA and other federal agencies have made this clear for years. [34]The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[35] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[36] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[37]

121. In materials Manufacturer Defendants produced, sponsored, or controlled, Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter

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Cost in the State of Michigan, 54(8) J. of Occupational & Environ. Med. 948-953 (2012).

[33] CDC Guidelines. at 20.

[34] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010) (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008) (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[35] CDC Guideline at 2.

[36] *Id.* at 18.

[37] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

iii. Omitting or mischaracterizing adverse effects of opioids

122. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and respiratory depression, Manufacturer Defendants routinely ignored the risks of hyperalgesia, a known serious risk associated with chronic opioid analgesic therapy, in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (often among veterans, for example, post-traumatic stress disorder and anxiety also can accompany chronic pain symptoms).

123. Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200, far fewer than from opioids).[38] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

124. Manufacturer Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of a competing class of analgesics: over-the-counter NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from

[38] The higher figure reflects deaths from all causes.

opioids. (*See, e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) (describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids); *Finding Relief: Pain Management for Older Adults* (Janssen) (stating that NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation).

125. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[39] Again, Manufacturer Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions resulting from a doctor visit increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions per visit fell from 38% to 29% .[40] Another study of an estimated 440 million visits for back pain over a period from 1999 to 2010 found that the use of NSAIDs fell from 36.9% to 24.5% of doctor visits resulting in prescriptions, while use of narcotics increased from 19.3% to 29.1%.[41] The CDC reports that the quantity of opioids dispensed per capita trebled from 1999 to 2015.[42]

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[39] Meredith Noble M, *et al.*, *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

[40] John N. Mafi et al., *Worsening Trends in the Management and Treatment of Back Pain*, 173(17) J. of the Am. Med. Ass'n Internal Med. 1573, 1573 (2013).

[41] *Id.*

[42] Vital Signs: Changes in Opioid Prescribing in the United States, 2006-2015, available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.

C. Manufacturer Defendants Continued to Tell Doctors that Opioids Could Be Taken in Ever Higher Doses Without Disclosing Their Greater Risks

126. Manufacturer Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to prescribe higher doses, rather than prescribing opioids for more frequent dosing.

127. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was still available after May 21, 2011 on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased... You won't 'run out' of pain relief."

128. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

129. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (e.g., doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose, even where

opioids are taken as recommended. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[43] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[44]

D. Endo Overstated the Efficacy of Abuse-Deterrent Opioid Formulations

130. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendant Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Endo's false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and enabled prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids— thereby further exacerbating the opioid epidemic in the City and elsewhere.

i. Endo's deceptive marketing of reformulated Opana ER

131. Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced in abuse-deterrent formulations, also made abuse deterrence a key to its marketing strategy and its ability to maintain and increase profits from Opana ER.

132. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its

[43] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[44] CDC Guideline at 16.

approval, the FDA advised Endo in January 2011 that it would not be permitted to market Opana ER, even after the reformulation, as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

133. In August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug, and also help preserve the market for branded Opana ER, which could be sold at non-competitive prices.

134. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare," would be lost.[45] The FDA responded that: "Endo's true interest

[45] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 Doc. 23

in expedited FDA consideration stems from business concerns rather than protection of the public health."[46]

135. Meanwhile, despite Endo's purported concern with public safety, court filings indicate that not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[47]

136. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

137. Over time, evidence confirmed that injection was becoming the preferred means of abusing Opana ER, which made Opana ER *less safe* than the original formulation. This occurred both because injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura ("TTP"),

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at 20 (D.D.C. Dec.14, 2012).

[46] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[47] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

which can cause kidney failure.[48] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500% according to data gathered in 2017.

138. Nevertheless, Endo continued to market the drug as tamper-resistant and deterring abuse. Indeed, upon information and belief, detailers for Endo have informed doctors in New Mexico and in and around the City that Opana ER was abuse-deterrent. In addition, upon information and belief, Endo sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by prescribers, claimed that while some outlying patients might find a way to abuse the drug, most would be protected.

139. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

140. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[49]

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[48] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

[49] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug*

The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[50] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[51]

141. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant." A January 2013 article in Pain Medicine News, based in part on an Endo press release, described Opana ER as "crush-resistant." This article was posted on the Pain Medicine News website, which was accessible to patients and prescribers nationally.

142. In a 2016 settlement with Endo, the New York Attorney General ("NY AG") found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to formulary committees and pharmacy benefit managers.

E. All Defendants Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Terminate Suspicious Orders

143. The Manufacturer Defendants created a vastly and dangerously larger market for opioids. All of the Defendants compounded this harm by facilitating the supply of far more opioids than could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to terminate orders that they

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Administration, et al., No. 1:12-cv-01936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[50] *Id.*

[51] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936 (Doc. 18-4) (D.D.C. Dec. 9, 2012).

knew or should have known were suspicious breached both their statutory and common law duties.

144. For over a decade, as the Manufacturer Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

i. All Defendants Have a Duty to Report Suspicious Orders and Terminate those Orders Unless Due Diligence Disproves Their Suspicions.

145. Statutes, regulations, and the common law impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

146. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By supplying the area in and around the City with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that duty and both created and failed to prevent a foreseeable risk of harm to the City. As the supply of opioids and the evidence of addiction to and abuse of these drugs grew, manufacturers, distributors, and pharmacies were again reminded of both the nature and harms of opioid exposure and use.

147. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion of prescription opioids, to speak accurately and truthfully.

148. Third, Defendants violated their statutory obligations under New Mexico law. As manufacturers and wholesale drug distributors of controlled substances, Defendants were required to register with the DEA. *See* 16.19.8.23(A)(4) and 24(C) NMAC. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." 16.19.20.48(A) NMAC. This same standard is promulgated in the criminal statues, specifically New Mexico's Controlled Substances Act. NMSA 1978, § 30-31-13(A)(l) (providing that "maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels" is a mandatory factor in board registration).

149. The New Mexico Controlled Substances Act and Administrative Code incorporate by reference relevant federal laws and regulations and impose registration duties upon manufacturers and distributors of controlled substances. *E.g.*, 16.19.8.13(1) NMAC; NMSA 1978, §§ 30-31- 13(C), 30-31-16(A). The State's regulations are intended to conform to federal regulations barring any impracticality. See NMSA 1978, § 26-1-18(A) (2005) ("The board shall conform the regulations promulgated under the New Mexico Drug, Device and Cosmetic Act, insofar as practical, with regulations promulgated under the federal act as defined in Section 26- 1-2 NMSA 1978.").

150. All Defendants must comply with statutory and regulatory duties to guard against diversion of highly addictive controlled substances into illicit channels. *See generally*, 16.19.6 NMAC (incorporating by reference federal law in pharmacy regulation); 16.19.20 NMAC (incorporating by reference federal law in controlled substances regulation).

151. The New Mexico Board of Pharmacy governs for the licensing of wholesale drug distributors in this State. NMSA 1978, § 61-11-6(A)(6) (2005). Under New Mexico regulations, "[w]holesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs." 16.19.8.13(F)(l) NMAC. "Wholesale drug distributors that deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations." 16.19.8.13(1)(2) NMAC.

152. Of particular import here, New Mexico regulations require that any diversion of a prescription drug be reported to the New Mexico Pharmacy Board, the FDA, and where applicable, to the DEA 16.19.8.13(F)(5) NMAC ("Wholesale distributors shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and FDA and where applicable, to the DEA"). The same duty exists under federal regulations, which are incorporated by reference. See NMSA 1978, §§ 30-31-13(C), 30-31-16(A); 16.19.8.13(1) NMAC (incorporating federal regulation by reference); 21 C.F.R. § 1301.74(b).[52] It is a crime to intentionally fail to furnish notifications required by the Controlled Substances Act and to intentionally omit any material information from any document required to be filed, or any record required to be kept, by the Act. NMSA 1978, § 30-3 l-24(A)(3).

153. Defendants have violated their duties under the New Mexico Controlled Substances Act and the New Mexico Administrative Code. See NMSA 1978, §§ 30-31-20, 30-31-24, 30-31- 25; 16.19.8 NMAC; 16.19.20 NMAC.

[52] To be crystal clear, the City cites federal statutes and federal regulations in this complaint to state the duty owed under New Mexico tort law, not to allege an independent federal cause of action or substantial federal question, both of which are expressly and unequivocally denied.

154. Opioids are Schedule II controlled substances. NMSA 1978, § 30-31-7(A). As such, opioids are defined as substances that pose a high potential for abuse that may lead to severe dependence. NMSA 1978, § 30-3 l-5(B).

155. Defendants violated their duties as licensed wholesale distributors by selling huge quantities of opioids that were diverted from their lawful, medical purpose, thus causing an opioid and heroin addiction and overdose epidemic in this City.

156. As the DEA advised Defendants in a letter to them dated September 27, 2006, Defendants, as wholesale distributors, are "one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[53]

157. Defendants violated New Mexico law when they violated a federal regulation that is incorporated into New Mexico law. 16.19.8.13(1) NMAC (which requires compliance with *inter alia* 21 C.F.R. § 1301.74(b)); 16.19.20.42 (requiring compliance with Part 1306.08 of the Code of Federal Regulations); 16.19.20.49 NMAC ("Security requirements which meet the federal DEA provision shall be deemed adequate under New Mexico Controlled Substances Act."); *see also* NMSA 1978, § 26-l-18(A). Defendants thereby had a duty to disclose suspicious orders:

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[53] *See* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enft Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006) [hereinafter Rannazzisi Letter] ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."),*filed in Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51.

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).[54] New Mexico law dictates the source of the duties owed. Therefore, even where a federal regulation informs some part of the case, that does not convert any state legal cause of action into any federal question, substantial or otherwise, because it is New Mexico law, and not any federal authority, that informs the existence of a duty.

158. "Suspicious orders" include orders of an unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

159. Thus, New Mexico regulations mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the requisite authority.

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[54] Once again, the City cites federal regulations in this complaint to state the duty owed under New Mexico law, not to allege an independent federal cause of action or substantial federal question, both of which are expressly and unequivocally denied.

Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert Defendants to potential problems.

160. Distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor who observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply – can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual, given the customer's history or its comparison to other customers in the area.

161. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under state law with respect to control of the supply chain of opioids. They must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

162. New Mexico statutes, regulations, and common law reflect a minimum standard of conduct and care that reasonably prudent manufacturers and distributors are required to meet. Together, these laws and industry guidelines make clear that Defendants must possess, and are

obligated to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

163. Further, these laws and industry standards make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

164. The FTC has recognized the unique role of Defendants McKesson, Cardinal, and AmerisourceBergen (the "Big Three"). Since their inception, the Big Three have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, the Big Three also offer their pharmacy, or dispensing, customers a broad range of added services. For example, they offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory-carrying costs. The Big Three are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support.[55] As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the range of additional services they offer, the Big Three have a unique insight into the ordering patterns and activities of their dispensing customers.

[55] *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.).

165. Like the Big Three, Walgreens, Wal-Mart, and CVS are uniquely positioned to know the ordering patterns and activities of their dispensing customers due to their roles as both distributors and national retail pharmacies. As national retail pharmacies, Walgreens, Wal-Mart, and CVS have vertically integrated models, which place them in a unique role, as they have both specific obligations under the CSA and a particular ability to spot, report, and stop filling suspicious orders. National retail pharmacies, like other distributors, must become registrants to legally distribute and/or dispense controlled substances. *E.g.*, 21 C.F.R. § 1301.11.[56] Pharmacy registrants, inasmuch as they act as distributors, are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a).[57]

166. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a).[58] Because pharmacies themselves are registrants, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

167. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify red flags of diversion and what to do when such red flags have been identified.

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[56] Here and elsewhere, all federal cites are only to duties incorporated into New Mexico law, and any independent federal cause of action or substantial federal question is unequivocally and expressly disavowed.

[57] Here and elsewhere, all federal cites are only to duties incorporated into New Mexico law, and any independent federal cause of action or substantial federal question is unequivocally and expressly disavowed.

[58] Here and elsewhere, all federal cites are only to duties incorporated into New Mexico law, and any independent federal cause of action or substantial federal question is unequivocally and expressly disavowed.

168. Specifically, DEA has identified several types of "unresolvable red flags" which, when presented to a pharmacist, may never be filled by the overseeing pharmacist. These unresolvable red flags include:

a. A prescription issued by a practitioner lacking valid licensure or registration to prescribe the controlled substances;

b. Multiple prescriptions presented by the same practitioner to patients form the same address, prescribing the same controlled substances in each presented prescription;

c. A high volume of patients presenting prescriptions and paying with cash;

d. A prescription presented to by a customer who has traveled significant and unreasonable distances from their home to see a doctor and/or to fill the prescription at the pharmacy.

169. When a pharmacist identifies any such red flags of diversion, the pharmacist must not fill the prescription. Filling a prescription without resolving such red flags is a violation of a pharmacist's legal duty and corresponding responsibility not to fill a prescription outside the usual course of practice and for other than a legitimate medical purpose.

170. New Mexico prescribing laws forbid a pharmacist from "[d]ispensing a prescription for a dangerous drug without an established practitioner-patient relationship." 16.19.4.9(C)(18) NMAC. Further, a pharmacist is required to perform a prospective drug review of every prescription issued and, prior to dispensing, "a pharmacist shall review the patient profile for the purpose of identifying" clinical abuse/misuse; therapeutic duplication; drug-drug

interactions; incorrect drug dosage; and incorrect duration of drug treatment. *See* 16.19.4.16(D)(1) NMAC.

171. Upon identifying any of the enumerated concerns, "a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing a controlled substance prescription monitoring report or another states' reports if applicable and available, and consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem." 16.19.4.16(D)(2) NMAC.

172. Additional types of resolvable red flags of diversion include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible as compared to most written prescriptions; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

173. Other signs of diversion can be observed through data that is gathered, consolidated, and analyzed directly by Pharmacy Defendants. That data allows national retail pharmacies, like Pharmacy Defendants, to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or

facilities that seem to engage in improper prescribing. Indeed, this data is sufficiently valuable in identifying "high prescribers" for purposes of marketing efforts, that companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies.[59] The majority of pharmacies sell these records.[60]

174. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

175. Manufacturer Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies, and from their purchase of data from commercial sources, such as IMS. Their extensive boots-on-the-ground through their sales force, allows Manufacturer Defendants to observe the signs of suspicious prescribing, such as lines of seemingly healthy patients, out-of-state license plates, and cash transactions, to name only a few. In addition, Manufacturer Defendants regularly mined data, including, upon information, chargeback data, that allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing that would have alerted them to suspicious prescribing. These information points gave Manufacturer Defendants insight into prescribing and dispensing conduct. Rather than using this information to prevent diversion and fulfill their obligations under New Mexico law, Manufacturer Defendants were part of a plan, effected in lock step with other Defendants, to increase the sales of opioids above any legitimate purpose, which caused the DEA to inflate beyond any therapeutic, medical, scientific, or research need,

[59] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[60] *Id.* at 389.

the quota for these prescription drugs.

176. Defendants have a duty to, and are expected to, be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. Defendants breached their duties by failing to: (a)control the supply chain; (b)prevent diversion; (c)report suspicious orders; and (d)halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

ii. Defendants Understood the Importance of Their Reporting and Due Diligence Obligations

177. All Defendants were well aware that they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

178. Recently, Defendant Mallinckrodt admitted in a settlement with DEA that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA."[61] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 CFR 1301.74(b)... [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."

179. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40

[61] https://www.justice.gov/usao-edmi/press-release/file/986026/download

years. The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association to which the Big Three (and Manufacturer Defendants) belong, and the National Association of Chain Drug Stores ("NACDS"), where Walgreens sits on the Board of Directors, have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[62] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain... are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[63]

180. The DEA also repeatedly reminded the Defendants of their obligations under federal law, mirrored in and incorporated by New Mexico law, to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[64] The Big Three Distributor Defendants have each attended at least one of

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[62] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[63] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances, filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

[64] Drug Enf't Admin., *Distributor Conferences*:

these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

181. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are "one of the key components of the distribution chain. If the closed system is to function properly... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ...the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[65] The DEA's September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[66] The same letter reminds distributors of the importance of their obligation to "be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes," and warns that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[67]

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https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *Manufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

[65] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

[66] *See id.*

[67] *See id.*

182. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[68] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (e.g., by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."[69]

iii. Despite Repeated Admonitions, Defendants Have Repeatedly Violated their Obligations

183. Distributor Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

184. Governmental agencies and regulators have confirmed (and in some cases Distributor Defendants have admitted) that Distributor Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

185. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that DEA issued final decisions in 178

[68] *See* 2007 Rannazzisi Letter.

[69] *See* id.

registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, McKesson, CVS, and Walgreens:

a. On April 24, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain
effective controls against diversion of hydrocodone;

c. On December 5, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia, Valencia, California, and Denver, Colorado;

h. On September 30, 2009, the DEA issued an Order to Show Cause against the Walgreens retail facility in San Diego, California ("San Diego Facility").

i. In April 2011, Walgreens entered into an Administrative Memorandum of Agreement ("2011 Walgreens MOA") with DEA in relation to its San Diego Facility. The MOA provided that "Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations.

j. On February 2, 2012, DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone;

k. On February 2, 2012, DEA issued *Orders to Show Cause and Immediate Suspension Orders* against Holiday C.V.S. L.L.C. d/b/a CVS/Pharmacy #00219 as well as CVS/Pharmacy #05195 for continually dispensing controlled substances to customers under circumstances indicating that the drugs were diverted from legitimate channels, misused, or abused. On August 31, 2012, the Administrator of DEA ordered the full revocation of both pharmacies' DEA registration for violations of the CSA and implementing regulations.

l. On September 14, 2012, DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Walgreens' Distribution Center in Jupiter, Florida.

m. On June 11, 2013, Walgreens agreed to pay $80 million in civil penalties to resolve DEA's investigations. It also entered into another Memorandum of Agreement with DEA in which it acknowledged that its distribution and dispensing practices were not fully consistent with its obligations under the CSA.

186. Both Defendant Cardinal Health and Defendant McKesson have also been fined for violations involving pharmacies or distribution facilities in New Mexico. On December 23, 2016, Cardinal Health agreed to pay a $34 million fine to DEA to settle allegations raised in the February 2, 2012 *Order to Show Cause and Immediate Suspension Order* that it violated the

CSA by failing to report suspicious orders sent from its Lakeland, Florida distribution centers to pharmacies in Florida.[70]

187. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders, including from its distribution facility in Landover, Maryland. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[71]

188. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required."[72] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into

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[70] The Settlement also included a related $10 million settlement in New York. *Id.*; Margie Manning, *Cardinal Health Agrees to $44 M Settlement in Lakeland, New York Cases*, Tampa Bay Business Journal (December 23, 2016).

[71] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter "2017 Settlement Agreement and Release"] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

[72] *Id.*

other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations . . . at the McKesson Distribution Centers" including the McKesson Distribution Center located in Landover, Maryland. These failures were direct violations of the 2008 McKesson MOA with the DEA. Upon information and belief, the McKesson facility located in Landover supplied opioids to the City.

189. As the *Washington Post* and *60 Minutes* recently reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[73] A DEA memo outlining the investigative findings in connection with the administrative case against 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[74]

190. Even the far lesser-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four states. This penalty, too, was far less severe than investigators had recommended; as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[75]

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[73] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[74] *Id.*

[75] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs," (Jan. 17, 2017)

191. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement]," as a DEA official working on the case noted.[76] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[77] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders placed by pharmacies, some of them knowingly supplying the drug rings."[78] "Instead, DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[79]

192. Further, in a *60 Minutes* interview from fall of 2017, former DEA agent Joe Rannazzisi described Wholesaler Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die."[80] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.

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https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

[76] *Id.* (alteration in original).

[77] *Id.* (quoting a March 30, 2015 DEA memo).

[78] *Id.*

[79] *Id.*

[80] Bill Whitaker, Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[81]

193. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[82] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[83]

194. At a hearing before the House of Representatives' Committee on Transportation and Infrastructure, Subcommittee on Economic Development, Public Buildings, and Emergency Management on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. However, in fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

195. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in

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[81] *Id.*

[82] *Id.*

[83] *Id.*

response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

196. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of only two pages. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c) examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—more than 9,500 pills *per day*.

197. Further, as referenced above, Walgreens has also been repeatedly penalized for its illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of Walgreens, including in New Mexico.

198. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

199. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black-market sales.[84]

[84] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-

200. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

201. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.[85]

202. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period. Yet Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.[86]

203. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause and Immediate Suspension Order, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on the number of prescriptions filled at the pharmacy to increase oxycodone

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record-settlement-80-million-civil-penalties-under-controlled.

[85] Order to Show Cause and Immediate Suspension of Registration, *In the Matter of Walgreens Co.* (Drug Enf't Admin. Sept. 13, 2012).

[86] *Id.*

sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.[87]

204. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

205. For example, in January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the context of soaring overdose deaths. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.[88]

206. Manufacturers had knowledge of diversion as well and have failed to comply with their obligations to report and decline suspicious orders, and stop detailing suspicious prescribers. Sales representatives learned that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

> Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

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[87] *Id.*

[88] *Id.*

207. Moreover, Manufacturer Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors.

208. Mallinckrodt also failed to report suspicious prescribing. A former Mallinckrodt sales representative reports that he regularly visited a doctor over the course of 5 years. The doctor has now been criminally indicted. During the visits, the representative saw the doctor's office overflowing with patients, some of whom waited for up to 8 hours to see the doctor, and heard them bragging about earning $70,000 from selling prescriptions written by the doctor. Despite having around 300 doctors on his call list, the former sales representative's supervisor at Mallinckrodt instructed the sales representative to spend half of his time with the doctor because of the sales potential due to the doctor's prescribing. The sales representative and his supervisor did not report the doctor because his prescribing was very high, and the company made a lot of money from his prescribing.

209. These examples demonstrate how Manufacturer Defendants' obligation to report suspicious prescribing ran head on into their marketing strategy. The goal of the marketing strategy was to increase these Defendants' profits by convincing more doctors to prescribe opioids in higher and higher doses for long term use. Thus, these Defendants did identify doctors who were their most prolific prescribers, but not to determine if their prescribing was suspicious

and, if so, report them. Defendants identified these prescribers to market to them and ensure they continued to prescribe more and more of Defendants' opioids.

210. Whenever examples of opioid diversion and abuse have drawn media attention, Manufacturer Defendants have consistently blamed "bad actors."

F. Defendants Worked Together to Sustain Their Market and Boost Their Profits

211. The Big Three, as leading wholesale distributors, had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock."[89] Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

212. Distributor Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer

[89] *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998).

more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits. Of course, increased sales volumes have also resulted in the oversupply of opioids and concurrent increases in addiction, overdose, and criminal diversion across the United States and in and around the City.

213. Upon information and belief, each of the Distributor Defendants also worked together, and with Manufacturer Defendants, through trade or other organizations, such as the HDA, the National Association of Chain Drugstores, and the Pain Care Forum ("PCF"),[90] to safeguard the market for opioids and the distribution of opioids.[91]

214. Although the entire HDA membership directory is private, the HDA website confirms that Defendants AmerisourceBergen, Cardinal, and McKesson, were members.[92] All of the Manufacturer Defendants were members as well.[93]

215. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Big Three with the opportunity to work closely with each other and with opioid manufacturers, confidentially, to develop and further their common purpose and interests.

216. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributors advertise these conferences as an opportunity to "bring together high-level executives, thought leaders and influential managers … to hold strategic business discussions on the most pressing industry issues."[94] The conferences

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[90] The Pain Care Forum is a lobbying organization.

[91] https://www.documentcloud.org/documents/3108980-PAIN-CARE-FORUM-Directory-04-2012.html (2012 document showing defendants or parents/affiliates)

[92] https://www.healthcaredistribution.org/about/membership/distributor (H.D. Smith would have been represented by Smith Drug Company, Div. J M Smith Corporation.)

[93] https://www.healthcaredistribution.org/about/membership/manufacturer.

[94] *Business and Leadership Conference—Information for Manufacturers*, Healthcare

also gave the Distributors and Manufacturer Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[95] The HDA and its conferences were significant opportunities for the Big Three to interact at a high level of leadership.

217. HDA members were eligible to participate on councils, committees, task forces and working groups, including:

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry

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Distribution Alliance, available at https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers (last accessed on Sept. 14, 2017).

[95] *Id.*

> knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[96]

218. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, shipping notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to "accurately and effectively exchange business transactions between distributors and manufacturers..." Upon information and belief, the Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

219. The Big Three also coordinated with each other and opioid manufacturers in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[97] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, as is described in this Complaint.

220. Distributor Defendants also worked together through HDA and National Association of Chain Drugstores ("NACDS"). The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to

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[96] Councils and Committees, Healthcare Distribution Alliance, (accessed on December 11, 2017), available at https://www.healthcaredistribution.org/about/councils-and-committees

[97] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Distributor Defendants worked together to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

221. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts to engage in the unlawful sale of prescription opioids.

222. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances ("Industry Compliance Guidelines") regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.

223. This statement by the HDA and the Industry Compliance Guidelines support the allegation that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately

prescribed and dispensed medications." Here, it is apparent that Defendants found the same balance – an overwhelming pattern and practice of failing to identify, report, or halt suspicious orders, and failure to prevent diversion.

224. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturer and Distributor Defendants did this through their participation in the PCF, HDA, and the NACDS.

225. Upon information and belief, the Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

G. Defendants Ignored Red Flags of Abuse and Diversion

226. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in DEA's confidential ARCOS database.[98] ARCOS, which stands for Automation of Reports and Consolidated Orders System, tracks controlled substances distribution based on data provided by manufacturers and distributors. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Distributor Defendants and Manufacturer Defendants, but has not been disclosed to the public.

227. Yet, publicly available information confirms that Defendants funneled far more opioids into and around the City than could have been expected to serve legitimate medical use,

[98] *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015).

and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting the City.

228. The City's information and belief rests upon the following facts:

(a) distributors have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) The Big Three, Manufacturer Defendants, regularly visit pharmacies and/or doctors to promote and provide their products and services, which allows them to observe red flags of diversion. Similarly, Walgreens has direct access to the transaction data of its chain of retail pharmacies.

(c) The Big Three together may account for more than 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

(d) Walgreens has been relatedly penalized for their illegal prescription opioid practices, and the wide-spread nature of these violations suggests they are the product of national policies and practices;

(e) Performance metrics and prescription quotas adopted by the national retail pharmacies such as Walgreens for its retail stores contributed to their failure. The result is both deeply troubling and entirely predictable: opioids flowed out of national retail pharmacies and into communities throughout the United States. The policies remained in place even as the epidemic raged.

229. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. Walgreens, for example, had direct access to the prescription rates of its retail pharmacies.

230. Distributors have a duty to know their customers and the communities they serve. Wholesale distributors, such as the Big Three, developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help distributors identify suspicious orders or customers who were likely to

divert prescription opioids.[99] The "know your customer" questionnaires informed distributors of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

231. According to testimony by a former Executive Chairman of the Board of Cardinal at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports, and, as explained above, Walgreens would have had this information from their own pharmacies.

H. Santa Fe County, the Area Within Which the City is Located, is a High Intensity Drug Trafficking Area Significantly Harmed by the Opioid Epidemic.

232. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around the City, should have investigated, terminated suspicious orders, and reported potential diversion to law enforcement.

233. The City has been designated a High Intensity Drug Trafficking Area by the Office of National Drug Control Policy.[100] Due to the vast openness of the geography, as well as

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[99] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Administration, available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf.

[100] *See* https://www.ncjrs.gov/ondcppubs/publications/enforce/hidta2001/nmex-fs.html

the proximity to Mexico, the region has been deemed "a major contributor to the flow of narcotics into and through" New Mexico.[101] The region continues to see increases in the amount of Mexican black tar heroin.[102]

234. Given the widespread abuse and misuse of opioids, it is unsurprising that some practitioners have begun to profit from this dangerous marketplace. Despite clear regulations under the New Mexico Administrative Code, some practitioners instead choose to violate their legal obligations and duties in order to profit from prescribing dangerous opioid controlled substances to patients.

235. Defendant Broderson pled guilty on September 19, 2016 to issuing patients multiple, often overlapping prescriptions for hydrocodone that significantly exceeded the medically recommended dosages.[103] Nurse Broderson also admitted to instructing patients to deliver the hydrocodone to her, and further admitted that the prescribing and retaining hydrocodone exceeded any legitimate medical purpose and was outside the usual course of professional practice. Nurse Broderson's conduct was further outside the usual course of professional practice as she had been operating as a solo practitioner providing psychiatric services, not pain management services.

236. In July 2018, Defendant Dr. Bray-Morris voluntarily surrendered his license to practice medicine in New Mexico.[104] Dr. Bray-Morris did so in light of the New Mexico Medical Board (the "Board") finding that he:

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[101] *Id.*

[102] *Id.*

[103] *See* https://www.justice.gov/usao-nm/pr/nurse-practitioner-santa-fe-sentenced-probation-unlawful-possession-controlled-substances

[104] *See* http://docfinder.docboard.org/nm_orders/Bray-Morris,%20John.pdf

a. Violated a prior stipulated agreement to abstain from personal use of opioid controlled substances;

b. Forged signatures on mandatory urine drug screenings;

c. Prescribed large amounts of controlled substances to patients without medical justification, specifically including placing patients on a potentially deadly regimen of at least one opioid, one benzodiazepine, and carisoprodol, a muscle relaxer;

d. Providing patient care deviating from the standard of care;

e. Failing to screen patients for substance abuse disorders;

f. Diverting the controlled substances he prescribed to patients for his own personal use;

g. Falsifying medical records; and

h. Failing to obtain prescription monitoring reports as required by law when treating chronic pain.

237. Nurse Broderson and Dr. Bray-Morris contributed to the region-wide opioid epidemic, encouraged by Manufacturer Defendants' misleading statements and marketing, facilitated by Pharmacy Defendants' failure to uphold their duties to monitor for red flags of diversion, and assisted by Distributor Defendants' failure to implement a system to monitor and report suspicious orders.

238. In response to the epidemic, New Mexico, in conjunction with federal law enforcement, has set up the New Mexico Heroin and Opioid Prevention and Education ("HOPE") Initiative. Nurse Broderson was a target of the HOPE Initiative investigation, which led to her arrest. In 2016, the HOPE Initiative led to the arrest of a couple charged with major drug trafficking charges, including conspiracy to distribute oxycodone, oxymorphone, and alprazolam. The couple twice distributed large quantities of opioid controlled substances in the

City, as well as six times in Bernalillo County, New Mexico. Ultimately, the couple pled guilty to the charges.[105]

239. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in and around the City.

I. Defendants Hid Their Lack of Cooperation With Law Enforcement and Falsely Claimed To Be Actively Working To Prevent Diversion

240. When a wholesaler or manufacturer does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action–or may not know to take action at all.

241. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

242. More generally, the Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these

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[105] *See* https://www.justice.gov/usao-nm/pr/albuquerque-couple-plead-guilty-prescription-drug-trafficking-and-money-laundering

dangerous drugs. For example, Defendant Cardinal claims that, We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone."[106] Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria."[107] Defendant Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse.[108] A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[109]

243. Similarly, Defendant McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help

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[106] Cardinal website, Ethics and Governance, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance.html.

[107] Cardinal website, Archives, Cardinal Health Values Statement, available at http://cardinalhealth.mediaroom.com/valuestatement.

[108] Cardinal website, available at http://www.cardinalhealth.com/en/about-us/corporate-citizenship/community-relations/population-health/rx-drug-misuse-and-abuse.html.

[109] Lenny Bernstein *et al., How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job'*, The Washington Post (Oct. 22, 2016), http://wapo.st/2vCRGLt.

prevent diversion.[110] Defendant McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our United States."[111]

244. Defendant AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances."[112] A company spokeswoman, Lauren Moyer, also provided assurance that, "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients."[113]

245. Walgreens also publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription. Citing these efforts, Walgreens promotes itself as committed to undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

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[110] McKesson website, Pharmaceutical Distribution for Manufacturers, available at http://www.mckesson.com/manufacturers/pharmaceutical-distribution/.

[111] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[112] https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

[113] https://www.wvgazettemail.com/news/cops and courts/drug-firms-fueled-pill-mills-in-rural-wv/article_14c8e1a5-19b1-579d-9ed5-770f09589a22.html

246. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[114]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

247. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, Distributor Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

248. These public statements created the false and misleading impression that the Distributor Defendants rigorously carried out their duty to report suspicious orders, exercised due diligence to prevent diversion of these dangerous drugs, and worked on their own accord to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

249. Manufacturer Defendants also misrepresented their compliance with legal duties and cooperation with law enforcement.

250. Mallinckrodt made misrepresentations regarding its efforts to fight opioid addiction. Mallinckrodt claims on its website to be "committed both to helping health care providers treat patients in pain and to fighting opioid misuse and abuse," and further asserts that,

[114] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

"In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances . . ."[115] The truth, of course, is that Mallinckrodt failed to put in place appropriate procedures to ensure suspicious orders would be reported and instead, continued to fill suspicious orders, which supplied far more opioids than were justified and led to diversion of opioids in and around the City and other cities, counties, and states.

251. Public statements by the Defendants and their associates created the false and misleading impression to regulators, prescribers, and the public that the Defendants rigorously carried out their legal duties, including their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and further created the false impression that these Defendants also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

J. By Increasing Opioid Prescriptions and Use, Defendants Collectively Fueled The Opioid Epidemic And Significantly Harmed The City and Its Residents

252. Manufacturer Defendants' misrepresentations and deceptive conduct prompted health care providers in and around the City to prescribe, patients to take, and payors to cover opioids for the treatment of chronic pain. Through their marketing Manufacturer Defendants overcame barriers to widespread prescribing of opioids for chronic pain. The Distributor Defendants recklessly distributed opioids and failed to meet their regulatory obligations in New Mexico.

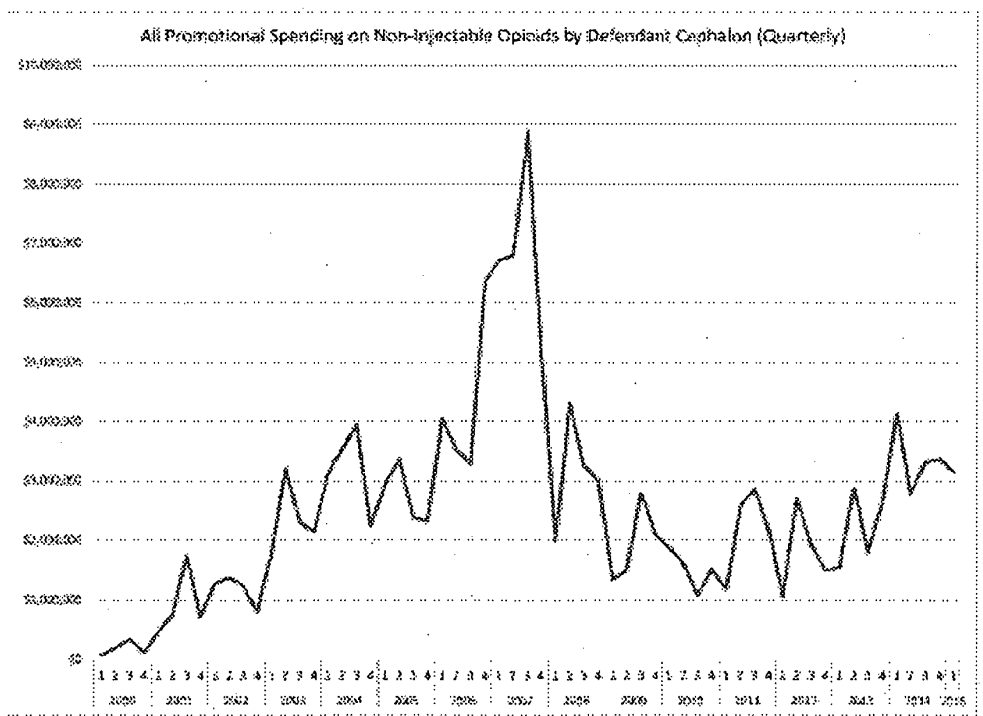
253. Defendants' deceptive marketing and illegal distribution practices substantially contributed to an explosion in the use of opioids across the United States. Approximately 20% of

[115] Mallinckrodt website, Our Programs, http://www2.mallinckrodt.com/Responsibility/Responsible_Use/Our_Programs/

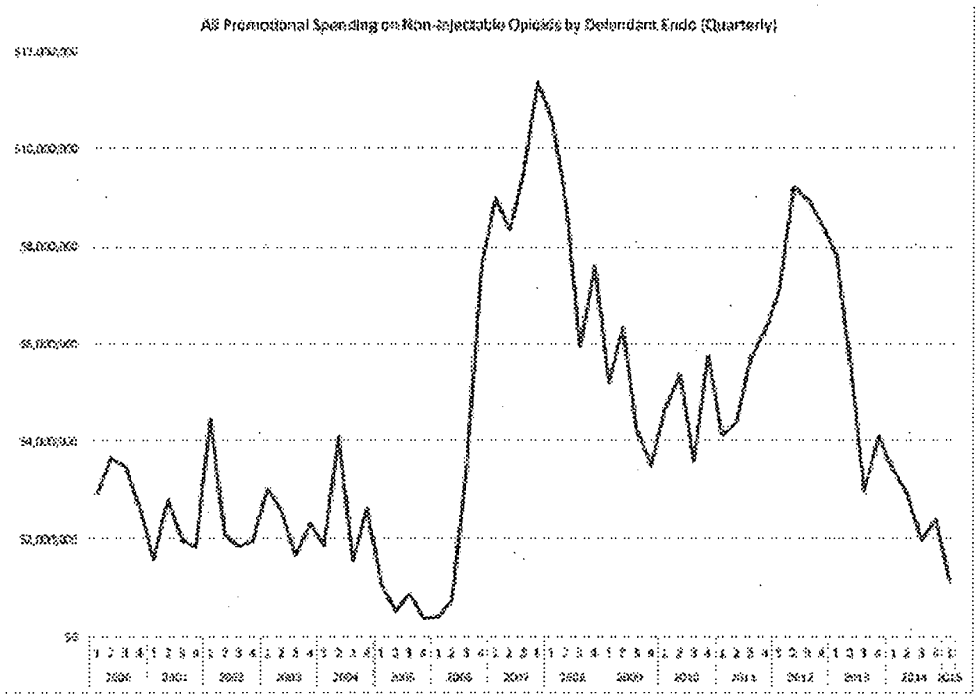
the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain. Since 2016, 20% of office visits have included the prescription of an opioid.

254. Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

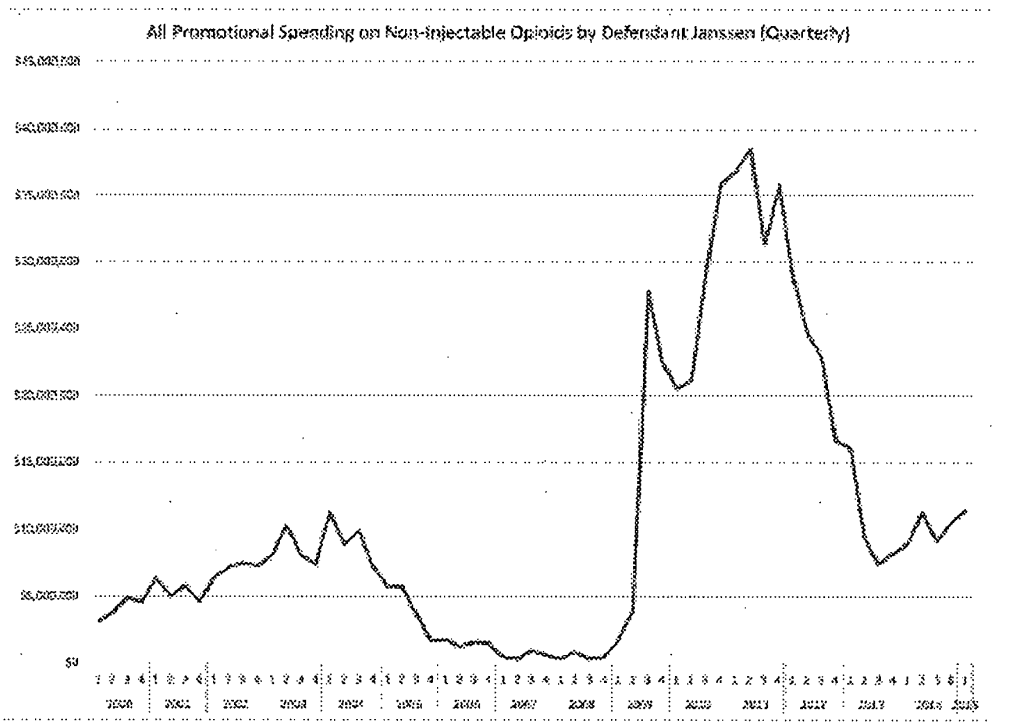
255. Teva's quarterly national spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



256. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



257. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



258. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in and around the City. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[116]

[116] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before the Senate Caucus on Int'l Narcotics Control*, May 14, 2014 Hr'g Testimony of Dr. Nora Volkow, available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

259. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[117]

260. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturer Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the CDC, opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

261. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the

[117] *See* Murthy, *supra*.

CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[118]

262. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[119]

263. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[120]The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[121]

K. The City Continues to Be Burdened with Significant Expenses as a Result of All Defendants' Malfeasance in Causing the Opioid Epidemic.

264. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the smaller decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily.

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[118] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *Increases in drug and opioid overdose deaths United States, 2000 2014*, Am. J. of Transplantation 16.4 (2016): 1323-1327.

[119] Theodore J. Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[120] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[121] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse*, New Engl. J. Med. (Apr. 14, 2016).

265. The overprescribing of opioids causes an increase in additional medical conditions. A growing number of people need medications aimed at treating secondary effects of opioids—including not only addiction and overdose, but also side effects like constipation and sedation. According to a recent analysis by the *Washington Post*, working-age women and men on opioids are much more likely to have four or more prescriptions from a physician (57% and 41%, respectively) than their counterparts who do not take opioids (14% and 9%, respectively). These secondary-effect medications—essentially, drugs to treat the effects of opioids—generated at least $4.6 billion in spending nationally in 2015, on top of $9.57 billion in spending on opioids themselves.

266. The deceptive marketing and overprescribing of opioids also has a significant detrimental impact on children. Prescription opioid use before high school graduation is related to a 33% increase in the risk of later opioid misuse.[122] Additionally, the adolescent misuse of opioid medications greatly predicts the later use of heroin.[123] However, according to the CDC Guidelines, there has been a significant increase in the prescribing of opioids to adolescents and children for headaches and injuries.[124]

267. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid

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[122] U.S. Pharmacist, *Legitimate Opioid Use Prior to High School Graduation Increase Abuse Risk*, available at https://www.uspharmacist.com/article/legitimate-opioid-use-prior-to-high-school-graduation-increases-abuse-risk.

[123] National Institute of Health, *Prescription Opioid Use is a Risk Factor for Heroin Use*, available at https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use.

[124] CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, *Morbidity and Mortality Weekly Report* 3 (March 18, 2016).

withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

268. Contrary to Defendants' misrepresentations, most of the illicit opioid use originates from prescribed opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet.

269. Those who are addicted to prescription opioid painkillers are 40 times more likely to become addicted to heroin. Prescription opioids, at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. Not surprisingly, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction.

270. Defendants' success in extending the market for opioids to new patients and chronic conditions also created an abundance of drugs available for non-medical or criminal use and fueled a new wave of addiction, abuse, and injury. Fentanyl is a relatively recent, even more

deadly problem stemming from the prescription opioid epidemic. Fentanyl is a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into communities across the United States. The City's prosecutors have noticed an increase in criminal cases involving the combination of heroin and fentanyl.

271. The burdens imposed on the City are not the normal or typical burdens of government programs and services. Rather, they are extraordinary costs and losses that are related directly to Defendants' illegal actions.

L. Defendants Fraudulently Concealed Their Misconduct

272. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of this, and likewise, Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

273. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded

marketing, third party advocates, and professional associations. Endo, Teva, Mallinckrodt, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Endo, Teva, Mallinckrodt, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

274. Manufacturer Defendants successfully concealed from the medical community, patients, and the City, facts sufficient to arouse suspicion of the claims that the City now asserts. The City did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

275. The Distributor Defendants also fraudulently concealed their misconduct. They have declined to publicly release the information they have provided to the DEA for the ARCOS database, which provides detailed tracking information about their shipments. In addition, as explained above, these Defendants publicly portray themselves as maintaining sophisticated technology as part of a concerted effort to thwart diversion, and publicly portray themselves as committed to fighting the opioid epidemic, while failing to prevent diversion.

276. Further, Defendants misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious prescribers and pharmacy orders.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

277. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

278. Defendants, individually and acting through their employees and agents, and in concert with each other, have intentionally, recklessly, or negligently engaged in conduct or omissions which endanger or injure the property, health, safety or comfort of the public in and around the City by their production, promotion, marketing, distribution, and sale of opioids for use by residents of the City. Defendants, individually and in concert with each other, have contributed to, and/or assisted in creating and maintaining a condition that is harmful to the health of thousands of the City's residents and interferes with the enjoyment of life in violation of New Mexico law. That the criminal public nuisance statute allows private citizens to abate a public nuisance under NMSA 30-8-8.

279. Prescription opioid abuse, addiction, morbidity, and mortality are a temporary public nuisance in the City, which remains unabated. The unlawful conduct by the Defendants has created these hazards to public health and safety, the public health epidemic, and the state of emergency described in this complaint.

280. The health and safety of the citizens of the City, including those who use, have used or will use opioids, as well as those affected by users of opioids, is a matter of great public interest and of legitimate concern to the City's citizens and residents. Defendants' acts and omissions offend, significantly and unreasonably interfere with, and cause damage to the public rights common to all, such as the public health, public safety, public peace, moral standards, and the public comfort. Defendants have control over their conduct in and around the City, and, therefore, willingly participated to a substantial extent in creating and maintaining the public nuisance.

281. Defendants knew, or should have known, that their promotion and irresponsible distribution of opioids (in violation of their monitoring and reporting obligations) would create or assist in the creation of a public nuisance.

282. Defendants are liable for a public nuisance because they acted without lawful authority in knowingly creating and maintaining opioid use at such volumes and degree as to create an epidemic, which clearly affects a number of citizens, is injurious to public health, safety, morals and welfare, and interferes with the exercise and enjoyment of public rights.

283. Each Defendant is liable for public nuisance because its conduct at issue has caused an unreasonable interference with a right common to the general public and the abatement statute allows "public officers or private citizens" to bring an action to abate a public nuisance. *City of Albuquerque v. State ex rel. Village of Los Ranchos de Albuquerque*, 1991-NMCA-015, ¶ 17, 111 N.M. 608, 808 P.2d 58 ("A public nuisance is a wrong that arises by virtue of an unreasonable interference with a right common to the general public.") (citing Restatement (Second) of Torts § 821B(1); further cit. om.). The Defendants' conduct described herein significantly interferes with public health, safety, peace, comfort, and convenience. All Defendants' actions were, at the least, a substantial factor in opioids becoming widely available and widely used for non-medical purposes. Manufacturer Defendants' actions were, at the very least, a substantial factor in deceiving doctors and patients about the risks and benefits of opioids for the treatment of chronic pain. Without Defendants' actions, opioid use, misuse, abuse, and addiction would not have become so widespread, and the opioid epidemic that now exists would have been averted or much less severe. Moreover, by failing to report or cease supplying known pill mills in and around the City, Defendants exacerbated the opioid crisis in the City, and failed to limit its reach.

284. In addition and independently, Defendants' conduct invades a legally protected interest. Defendants' conduct constitutes an unreasonable interference because *inter alia* each Distributor Defendant has violated New Mexico law. *E.g., inter alia,* NMSA 1978, §§ 30-31-1 to -41; 61-11-6; 16.19.8.13, 16.19.20.48 NMAC. The Distributor Defendants have permitted dangerous drugs under their control to be diverted for illicit purposes such as to injure the City and its residents.

285. The Manufacturer Defendants have violated New Mexico law. NMSA 1978, §§ 30-31-1 to -41; 30-16-6. These Defendants conducted a fraudulent campaign to misrepresent the safety and efficacy of opioid drugs and to ensure their widespread use for chronic pain knowing that Defendants were specifically misrepresenting the high risk of severely harmful addiction.

286. All Defendants knew or should have known that distributing or selling opioids in ways that facilitated and encouraged their flow into the illegal secondary market, distributing or selling opioids without maintaining effective controls against diversion, choosing not to stop or suspend shipments of suspicious orders, choosing not to report suspicious prescribing, distributing or selling opioids to pill mills when Defendants knew or should have known the opioids were being prescribed by pill mills, and filling prescriptions for opioids despite the existence of unresolvable red flags of diversion would create or assist in the creation of a public nuisance.

287. Because Defendants have maintained their opioid drug selling activities contrary to law, and because Defendants' conduct has unreasonably interfered with a right common to the general public, Defendants are liable for public nuisance per se. *See Espinosa v. Roswell Tower, Inc.*, 1996-NMCA-006, ¶ 10, 121 N.M. 306, 910 P.2d 940 ("An activity conducted or maintained contrary to law may be a public nuisance per se when the activity unreasonably interferes with a right common to the general public.").

288. Defendants' unreasonable interference with a right common to the public is of a continuing nature. Defendants are aware, and at a bare minimum certainly should be aware, of the unreasonable interference that their conduct has caused in the City. Defendants are in the business of manufacturing or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because inter alia these drugs are defined under New Mexico law as substances posing a high potential for abuse and severe addiction. NMSA 1978, §§ 30-31-5(B), 30-3l-7(A). Defendants created an absolute nuisance. Defendants' actions created and expanded the abuse of opioids, drugs specifically codified as constituting severely harmful substances.

289. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The harm is ongoing, producing long-lasting damage. Defendant's conduct is not insubstantial or fleeting. It has caused deaths, serious injuries, and a severe disruption of public peach, health, order, and safety.

290. Defendants' conduct directly and proximately caused injury to the City and its residents. The City suffered special injuries distinguishable from those suffered by the general public. As discussed herein, the City has incurred substantial costs from investigating, monitoring, treating, policing, and attempting to remediate the opioid epidemic.

291. The City's fire department spent over $212,000 in the Fire-Years 2017-2018 on opioid overdose patients. From January 1 2011 to December 31 2018 the fire department documented naloxone administration in 1507 patient encounters and spent $23,755 on naloxone alone in the Fire Years 2014 – 2015 through Fire Years 2017 – 2018, These costs represent the direct cost for naloxone and do not include other/indirect costs of administering it, such as IV supplies, nasal administration devices and needles, among other equipment.

292. The community services department has expended $1,251,000 in Children Youth Commission and Human Services Committee funding since 2009 on non-profits in the City to provide opioid education, opiate use prevention services, and treatment for youth and adults, which expenditure has been necessitated by the actions of defendants.

293. The City's Police Department's LEAD Program "Law Enforcement Assisted Diversion Program," targeting the 100 eligible population who cause property crime offenses due to their opioid use, costs $4.2million.

294. The staggering rates of opioid and heroin use resulting from the Distributor Defendants' abdication of their gate-keeping duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to the entire community that includes, but is not limited to:

a. The high rates of use leading to unnecessary opioid abuse, addiction, overdose, injuries, and deaths.

b. Nor have children escaped the opioid epidemic unscathed. Easy access to prescription opioids made opioids a recreational drug of choice among the City's teenagers. Even infants have been born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts.

c. Even those residents of the City who have never taken opioids have suffered from the public nuisance arising from Defendants' abdication of their gate-keeper duties and fraudulent promotions. Many residents have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids.

d. The opioid epidemic has increased health care costs for the City's employees and the City's residents.

e. Employers have lost the value of productive and healthy employees.

f. Defendants' conduct created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury.

g. Defendants' dereliction of duties and/or fraudulent misinformation campaign pushing dangerous drugs resulted in a diverted supply of narcotics to sell, and the ensuing demand of addicts to buy them. More pills sold by Defendants led to more addiction, with many addicts turning from prescription pills to heroin. People addicted to opioids frequently require increasing levels of opioids, and many turned to heroin as a foreseeable result.

h. The diversion of opioids into the secondary, criminal market and the increased number of individuals who abuse or are addicted to opioids increased the demands on health care services and law enforcement in the City.

i. The significant and unreasonable interference with the public rights caused by Defendants' conduct taxed the human, medical, public health, law enforcement, and financial resources of the City.

j. Defendants' interference with the comfortable enjoyment of life in the City is unreasonable because there is little social utility to opioid diversion and abuse, and any potential value is outweighed by the gravity of the harm inflicted by Defendants' actions.

295. The City has sustained specific and special injuries because its damages include *inter alia* health services and law enforcement expenditures, as described in this Complaint. The public nuisance, i.e., the opioid epidemic, created, perpetuated, and maintained by all Defendants can be abated and further recurrence of such harm and inconvenience abated.

WHEREFORE, the City. seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, abatement of the public nuisance, payment to the City of monies necessary to abate the public nuisance and any other monetary compensation to which the City may be entitled, compensatory and/or punitive damages and any other damages as allowed by law, attorney fees and costs, and pre- and post-judgment interest.

COUNT II
Racketeering Act
(Against Manufacturer Defendants)

296. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

297. The City has standing pursuant to NMSA 1978, § 30-42-6(A), because the City has sustained injury as outlined in this Complaint.

A. The Opioids Marketing Enterprise.

298. Defendants formed an association-in-fact enterprise (occ. "Opioids Marketing Enterprise"), and participated in the affairs of this enterprise when distributing highly dangerous, addictive opioid drugs in New Mexico. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; and (b) the Front Groups, including their employees and agents; and (c) the KOLs.

299. Defendants, the Front Groups, and the KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of profiting from the sale of opioids, through a pattern of racketeering activity.

300. Defendants conducted the Opioids Marketing Enterprise, and participated in the enterprise, by engaging in a pattern of racketeering activity.

301. Defendants received proceeds derived from a pattern of racketeering activity in which Defendants participated, and used or invested at least a part of the proceeds or the proceeds derived from the investment or use, in the acquisition of an interest in, or the establishment or operation of, the Opioids Marketing Enterprise.

302. Defendants engaged in a pattern of racketeering activity to acquire or maintain an interest in or control of the Opioids Marketing Enterprise.

303. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systemic links for a common purpose: to ensure the prescription of opioids for chronic pain.

304. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented - either affirmatively or through half-truths and omissions - to the general public, the City, and New Mexico consumers, the risks and benefits of using opioids for chronic pain. The Opioids Marketing Enterprise concealed from the public, the City, and New Mexico consumers, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

305. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

306. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids.

Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers and the City. But for the Opioid Marketing Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioids Marketing Enterprise's scheme and reaped substantial benefits.

307. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

308. The Front Groups and KOLs participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity including multiple instances of fraud, they knowingly made material misstatements or omissions to City and City area physicians, consumers, the City, and the general public in furtherance of the fraudulent scheme, including but not limited to the facts that:

a. it was rare, or there was a low risk, that Defendants' opioids could lead to addiction;[125]

b. the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;[126]

[125] APF, *Treatment Options* (sponsored by Cephalon).

c. doctors could increase opioid dosages indefinitely without added risk;[127]

d. long-term opioid use improved patients' function and quality of life;[128] and,

B. Conduct of the Opioids Marketing Enterprise.

309. From approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation and management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

b. Defendants selected, cultivated, promoted and paid the KOLs based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

f. Defendants sponsored CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

g. Defendants developed and disseminated pro-opioid treatment guidelines;

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[126] *See, e.g.*, Mark S. Wallace, M.D., Dir., Ctr. for Pain Medicine, Univ. of Cal. San Diego, National Initiative on Pain Control, *Opioid Analgesic Slide Module* (sponsored by Endo).

[127] *Id.*; APF, *Treatment Options* (sponsored by Cephalon); McCaffery & Pasero (editor is a key opinion leader for Endo).

[128] APF, *Treatment Options* (sponsored by Cephalon); Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* (2007); NIPC, *Persistent Pain and the Older Patient* (2007).

h. Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;

i. Defendants concealed their relationship to and control of Front Groups and KOLs from the City and the public at large; and

J. Defendants intended that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

310. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to Front Groups and payments to KOLs to ensure that their representations were consistent with Defendants' messaging nationwide and throughout the State of New Mexico and in the City. Front Groups were dependent on Defendants for their financial support, and KOLs were professionally dependent on Defendants for the development and promotion of their careers.

311. The Front Groups also participated in the conduct of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages;

b. The Front Groups distribute promotional and other materials claiming that opioids could be safely used for chronic pain, and the benefit of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

312. The KOLs also participated in the conduct of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages;

b. The KOLs distributed promotional and other materials which claimed that opioids

could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

313. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment for prescriptions of Defendants' opioids by New Mexico patients and the City. The Scheme was a continuing course of conduct, and many aspects of it continue through to the present.

a. Pattern of Racketeering Activity.

314. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering as defined in NMSA 1978, Section 30-42-3. Defendants' conduct as described above constitutes fraud chargeable or indictable under the laws of New Mexico and punishable by imprisonment for more than one year, which is defined as racketeering. NMSA 1978, § 30-42-3(A)(6).

315. "Fraud consists of the intentional misappropriation or taking of anything of value that belongs to another by means of fraudulent conduct, practices or representations." NMSA 1978, § 30-16-6. Here, Defendants intended to and did by means of fraudulent misrepresentations regarding the benefits of opioid prescriptions for treating chronic pain, succeed in misappropriating City funds, including, for example:

a. Costs of prescriptions;

b. Public employees' health insurance prescription coverage costs;

c. Retired public employees' group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, NMSA 1978, § 10-7C-8 (1990); and,

d. Other employees' health and benefit costs.

316. Defendants made the misrepresentations regarding the opioids' benefits with actual fraudulent intent to deceive prescribers in the City, New Mexico government payor programs *(inter alia* Medicaid), and the City's patients. Defendants' deception was massively successful.

317. Defendants' racketeering activities also included violations of the New Mexico Controlled Substances Act, Sections 30-31-20 to -22, and each act is chargeable or indictable under the laws of New Mexico and punishable by imprisonment for more than one year. *See* NMSA 1978, § 30-42-3(A)(13) (defining controlled substance trafficking as racketeering); § 30-42-3(A)(19) (defining controlled substance distribution as racketeering). The Manufacturer Defendants did not act in accordance with the New Mexico Controlled Substances Act because they did not act in accordance with registration requirements as provided in that Act. *See* **NMSA** 1978, §§ 30-31-12(B), 30-31-13(C), 30-31-16(A); 30-31-24(A)(2, 3), 30-31-25(A)(4). Among other infractions, Defendants did not comply with 21 U.S.C. § 823 and its attendant regulations *(e.g.,* 21 C.F.R. § 1301.74), which are incorporated into New Mexico statutes or the New Mexico Pharmacy Board regulations. The Defendants failed to furnish notifications required under the Substances Control Act. NMSA 1978, § 30-31-24(A)(3). Relatedly, the Defendants omitted required reports. NMSA 1978, § 30-31-25(A)(4). Trafficking in controlled substances in violation of Section 30-31-20 is defined as "racketeering." § 30-42-3(A)(13). Distribution of controlled substances in violation of Sections 30-31-21 and 30-31-22 is defined as "racketeering." NMSA 1978, § 30-42-3(A)(19).

318. The pattern of racketeering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

319. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

320. Many of the precise dates of the Defendants' criminal actions at issue here have been hidden and cannot be alleged without access to Defendants', the Front Groups' and the KOLs' books and records. Indeed, an essential part of the successful operation of the Opioids Marketing Enterprise alleged herein depended upon secrecy.

321. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in the City. Defendants, the Front Groups and the KOLs calculated and intentionally crafted the opioids marketing scheme to increase and maintain their increased profits, without regard to the effect such behavior had on consumers in the City. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

322. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to consumers in the City, Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

323. It was foreseeable to Defendants that the Front Groups and the KOLs would distribute publications and otherwise misrepresent that the benefits of using opioids for chronic pain outweighed the risks of doing so.

324. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

a. Damages

325. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the City to be injured in its business and property because the City paid for opioid prescriptions for chronic pain for which they would not otherwise have paid and have sustained other damages as described in this Complaint.

326. The City's injuries were proximately caused by Defendants' racketeering activities. But for the misstatements made by the Defendants, the Front Groups, and the KOLs and the scheme employed by the Opioids Marketing Enterprise, the City would not have paid for opioid prescriptions.

327. The City's injuries were directly caused by Defendants' racketeering activities. Although the misstatements made by the Front Groups and the KOLs in furtherance of the Opioids Marketing Enterprise were directed primarily to health care providers, those providers did not have to make payments for opioids prescribed for chronic pain. Therefore, New Mexico health care providers did not suffer the same injuries alleged in the Complaint.

328. The City was most directly harmed, and there is no other Plaintiff better situated to seek a remedy for the economic harms at issue here.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for compensatory damages, treble actual damages, injunctive relief, and any and all damages allowed by law to be paid by Defendants, attorney fees and costs, costs of investigation, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT III
Fraudulent Misrepresentation
(Against Manufacturer Defendants)

329. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

330. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to the City and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

331. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions; in falsely promoting abuse-deterrent formulations as reducing abuse; in falsely claiming that OxyContin provides 12 hours of relief; and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids, Manufacturer Defendants have engaged in misrepresentations and knowing omissions of material fact.

332. Specifically, misrepresentations or omissions include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

333. By engaging in the acts and practices alleged herein, Defendants omitted material facts that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

g. Manufacturer Defendants failed to report suspicious prescribers;

334. Defendants' statements about the use of opioids to treat chronic pain and/or non-cancer pain conditions were false and not supported by or contrary to the scientific evidence.

335. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead City prescribers and consumers.

336. Defendants knew at the time that they made their misrepresentations and omissions that they were false.

337. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

338. Healthcare providers and residents in the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

339. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, it would have undertaken efforts to avoid payments of related claims.

340. The Defendants' misrepresentations caused the City to fail to recognize that the problems at issue here arise from a man-made epidemic, or to understand the nature and gravity of the harms. The City relied on the Defendants to act as responsible corporate citizens, and Defendants' conduct as described herein prevented the City from taking action in attempting to address root causes and otherwise to ameliorate the public health crisis.

341. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

342. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT IV
Negligent Misrepresentation
(Against Manufacturer Defendants)

343. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

344. Manufacturer Defendants individually and acting through their employees and agents, made misrepresentations and omissions of facts material to Plaintiff and its residents to induce them to purchase, administer, and consume opioids as set forth in detail above.

345. Defendants had a duty to exercise reasonable care in marketing and selling highly dangerous opioid drugs in and around the City.

346. Defendants negligently asserted false statements and omitted material facts regarding the benefits of and evidence for the use of opioids for chronic pain, while understating their very serious risks, including the risk of addiction.

347. These false statements included but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with *more* opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that opioid doses can be increased until pain relief is achieved;

e. Defendants' claims that opioids differ from NSAIDS in that they have no ceiling dose;

f. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

g. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

h. Endo's claims that abuse-deterrent opioids reduce tampering and abuse;

i. Endo's claims that they cooperate with and support efforts to prevent opioid abuse and diversion; and

348. Defendants intended that the City and its residents would rely on their misrepresentations and omissions, knew that the City and its residents would rely on their misrepresentations, and that such reliance would cause the City to suffer loss.

349. Healthcare providers and residents in and around the City reasonably relied on Defendants' misrepresentations and omissions in writing, filling, and using prescriptions for Defendants' opioids, and the City and its agents reasonably relied on these misrepresentations and omissions in covering and paying for Defendants' opioids for chronic pain.

350. Had the City known that Defendants misrepresented the risks, benefits, and evidence regarding the use of opioids for chronic pain, the City would have undertaken efforts to avoid payments of related claims.

351. By reason of their reliance on Defendants' misrepresentations and omissions of material fact the City suffered actual pecuniary damage.

352. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT V
Negligence and Negligence Per Se
(Against all Defendants)

353. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein. A negligence claim requires the existence of a

duty from a defendant to a plaintiff, breach of that duty, which is typically based upon a standard of reasonable care, and the breach being a proximate cause and cause in fact of the plaintiff's damages. We apply a four-part test to determine whether a negligence per se instruction is appropriate in a given case.

> (1) [T]here must be a statute which prescribes certain actions or defines a standard of conduct, either explicitly or implicitly, (2) the defendant must violate the statute, (3) the plaintiff must be in the class of persons sought to be protected by the statute, and (4) the harm or injury to the plaintiff must generally be of the type the legislature through the statute sought to prevent.

Heath v. La Mariana Apartments, 2008-NMSC-017, ¶ 7, 143 N.M. 657, 659, 180 P.3d 664, 666; *Herrera v. Quality Pontiac*, 2003-NMSC-018, ¶7. All elements exist here.

354. Manufacturer Defendants, and Distributor Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, and distributing highly dangerous opioid drugs in and around the City.

355. Manufacturer Defendants, and Distributor Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

356. Manufacturer Defendants, and Distributor Defendants are part of a limited class of registrants authorized to legally market, sell, and distribute controlled substances, which places them in a position of great trust and responsibility vis-a-vis the City. Their duty cannot be delegated.

357. In addition, Manufacturing and Distributor Defendants each had a duty under New Mexico law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report suspicious orders of

opioids, and not to fill suspicious orders unless and until due diligence had eliminated the suspicion.

358. The Pharmacy Defendants have additional duties under the law to refuse to fill any prescription for a controlled dangerous substance which they have reason to believe, or should have reason to believe, was not issued for a legitimate medical purpose in the usual course of the prescriber's practice. The Pharmacy Defendants had a persistent duty to identify red flags of diversion, and to refuse to fill all such prescriptions presenting red flags.

359. Dr. Bray-Morris and Nurse Broderson had unique duties under the law, as licensed health care professionals, not to prescribe outside the usual course of practice and for other than a legitimate medical purpose.

360. The New Mexico statutes and regulations at issue, including without limitation NMSA 1978, Section 26-1-18; and Sections 16.19.8.13 and 16.19.20.48 NMAC, are public safety laws. As such, these laws were intended to protect the public welfare and safety, and the City is the proper Plaintiff to enforce these laws. Defendants have duties under inter alia these laws to protect against diversion of prescription opioids for non-medical and non-scientific purposes and to guard against, prevent, and report suspicious orders of opioids.

361. Upon information and belief, each of these Defendants repeatedly breached its duties.

362. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

363. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City and its communities; increased expenses for the City for healthcare, emergency response, and public safety.

364. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of New Mexico law for Manufacturer Defendants, and Distributor Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

365. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively marketing highly addictive opioids for chronic pain by misrepresenting the risks and benefits of such use would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants Reasonably prudent manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

366. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

367. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from the negligence of all Defendants. It does not seek damages which may have been suffered by individual citizens of the City for wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by the actions of Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants.

368. These Defendants breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

369. The misconduct alleged in this case is ongoing and persistent.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VI
Gross Negligence and Punitive Damages
(Against all Defendants)

370. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

371. By engaging in the above-described unfair acts or practices, Defendants acted wantonly or oppressively or with such malice as implies a spirit of mischief or criminal indifference to civil obligations. Defendants' conduct also was willful, reckless, and/or fraudulent. *See Clay v. Ferrellgas, Inc.*, 1994-NMSC-080, ¶ 12, 118 N.M. 266, 881 P.2d 11 ("To be liable for punitive damages, a wrongdoer must have some culpable mental state, . . . and the

wrongdoer's conduct must rise to a willful, wanton, malicious, reckless, oppressive, or fraudulent level, ...") (citations omitted).

372. All the Defendants have a duty to exercise reasonable care in manufacturing, marketing, selling, distributing, and dispensing highly dangerous opioid drugs in and around the City.

373. All the Defendants have a duty to exercise reasonable care under the circumstances. This includes a duty not to cause foreseeable harm to others. In addition, these Defendants, having engaged in conduct that created an unreasonable risk of harm to others, had, and still have, a duty to exercise reasonable care to prevent the threatened harm.

374. All the Defendants are part of a limited class of registrants authorized to legally market, sell, distribute, and dispense controlled substances, which places them in a position of great trust and responsibility vis a vis Plaintiff. Their duty cannot be delegated.

375. In addition, Manufacturer Defendants, Distributor Defendants, and Pharmacy Defendants each had a duty under New Mexico law, which incorporates the federal Controlled Substances Act, to maintain effective controls against diversion of prescription opioids, to report suspicious orders of opioids, to not to fill suspicious orders unless and until due diligence had eliminated the suspicion, and to not fill prescriptions issued outside the usual course of medical practice and for other than a legitimate medical purpose.

376. Upon information and belief, each of these Defendants repeatedly and intentionally breached its duties.

377. All Defendants acted with wanton and reckless disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

378. The foreseeable harm from a breach of these duties is the sale, use, abuse, and diversion of prescription opioids.

379. The foreseeable harm from a breach of these duties also includes abuse, addiction, morbidity and mortality in the City's communities.

380. Reasonably prudent manufacturers and distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of New Mexico law for Manufacturer Defendants, and Distributor Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse to prevent precisely these types of harms.

381. Reasonably prudent manufacturers of pharmaceutical products would know that aggressively pushing highly addictive opioids for chronic pain by misrepresenting the risks and benefits of such use would result in the severe harm of addiction, foreseeably causing patients to seek increasing levels of opioids and to turn to the illegal drug market as a result of a drug addiction that was foreseeable to the Manufacturer Defendants. Reasonably prudent

manufacturers would know that failing to report suspicious prescribing, particularly while assuring the public of their commitment to fighting the opioid epidemic, would exacerbate problems of diversion and non-medical use of prescription opioids.

382. Reasonably prudent distributors would know that failing to report suspicious orders would lead to diversion of the opioids they shipped. Reasonably prudent distributors would also know that filling such orders without first exercising due diligence would create an environment in which diversion would occur.

383. Reasonably prudent pharmacies would know that filling a prescription presented with unresolvable red flags of diversion would lead directly to diversion of opioid controlled substances.

384. Reasonably prudent health care practitioners would know that dispensing prescriptions for dangerous and highly-abused opioid controlled substances would lead directly to abuse, misuse, diversion into illicit channels, addiction, and potentially death.

385. The City seeks economic losses (direct, incidental, or consequential pecuniary losses) and punitive damages resulting from the gross negligence of all Defendants. The City does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by these Defendants' actions.

386. All Defendants' conduct as described in this complaint constitutes an intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another, including the City, and also implies a thoughtless disregard of the consequences without the exertion of any effort to avoid them. All Defendants have acted wantonly and willfully by inflicting injury intentionally or, alternatively, they have been utterly indifferent to the rights of others, including the City. They acted as if such rights did not exist.

387. All Defendants conduct as described in this Count demonstrates wanton and willful disregard for others, including the City, and justifies an award of punitive damages.

388. These Defendants' breach of the duties described in this Count directly and proximately resulted in the injuries and damages alleged by the City.

389. The misconduct alleged in this case is ongoing and persistent.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including judgment for monetary damages, injunctive relief, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorney fees and costs, and pre- and post-judgment interest and such other relief as this Court deems just and equitable.

COUNT VII
Unjust Enrichment
(Against All Defendants)

390. The City incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

391. To prevail on a claim for unjust enrichment under New Mexico law, a plaintiff must show that another has been knowingly benefitted at one's expense in a manner such that allowance of the other to retain the benefit would be unjust. *City of Rio Rancho v. Amrep Sw. Inc.*, 2011-NMSC-037, ¶ 54, 150 N.M. 428, 260 P.3d 414, 429 (citation omitted).

392. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the City.

393. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

394. The City has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

395. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

396. These expenditures have helped sustain Defendants' businesses.

397. The City has conferred a benefit upon Defendants by paying for the cost of the harms caused by Defendants' improper marketing and distribution practices.

398. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

399. The City has paid for the cost of the harms caused by Defendants' improper marketing and distribution practices, and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Manufacturer Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, all Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification.

400. Defendants have unjustly retained benefits to the detriment of the City, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

401. Defendants' misconduct alleged in this case is ongoing and persistent.

402. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence.

403. The City has incurred expenditures for special programs over and above Plaintiff's ordinary public services.

WHEREFORE, the City seeks all legal and equitable relief as allowed by law, including disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law and such other relief as this Court deems just and equitable.

PRAYER FOR RELIEF

WHEREFORE, the City requests the following relief:

a. A finding that by the acts alleged herein, Defendants have created a public nuisance;

b. For an injunction permanently enjoining Defendants from engaging the acts and practices that caused the public nuisance;

c. For an order directing Defendants to abate and pay damages for the public nuisance;

d. For a finding that Defendants were negligent and grossly negligent;

e. For compensatory damages in an amount sufficient to fairly and completely compensate for all damages alleged herein;

f. For treble actual damages;

g. For punitive damages;

h. For restitution or disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

i. For costs, filing fees, pre and post judgment interest, and reasonable attorney's fees; and

j. For all other and further relief to which this Court finds it is entitled.

DATED: September 16, 2019

The City of Santa Fe, New Mexico

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* indicates *Pro Hac Vice* to be submitted

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